LINDE MEDICAL SENSORS AG

MicroGas 7650-500

rapid

SERVICE MANUAL

CE 0123

SERVICE MANUAL

MicroGas 7650-500
rapid

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SALES AND SERVICE

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In order to maintain and improve standards of manufacturing, methods of functioning and to increase reliability, Linde Medical Sensors equipments are periodically reviewed. For this reason, the contents of this publication are subject to change without notice.

Manufactured by:

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QUALITY, RELIABILITY AND SAFETY

This equipment has been designed with an emphasis on QUALITY, RELIABILITY AND SAFETY, but Linde Medical Sensors AG will accept responsibility for these aspects only when the following conditions are met:

a) Electrical installations of the room or building in which the equipment is to be used must comply with regulations specified by the country in which the equipment is to be used.

b) The equipment is used in accordance with the instructions for use provided by Linde Medical Sensors.

c) All modifications and repairs to the equipment are carried out by Linde Medical Sensors personnel, their authorized agents or Linde Medical Sensors trained hospital technicians.

d) Modifications must not be carried out unless they conform with approved Engineering Service Information issued according to the appropriate Linde Medical Sensors procedure.

e) Equipment installation must be carried out in accordance with local requirements regarding responsibility and warranty.

f) Only Linde Medical Sensors transcutaneous sensors and accessories may be used. Other transcutaneous sensors and accessories may cause improper monitor performance.

The equipment has been designed and manufactured to meet the requirements of the following safety standards:
EN 60601-1, EN 60601-1-2, IEC 601-2-23, UL 2601-1 and CSA C22.2 No. 601.1-M90

CE 0123

This equipment is fully in conformance with the requirements of the Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices.

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PRECAUTIONS

Definitions

A **WARNING!** indicates that there is a risk of injury to the patient or to the operator.

A ***CAUTION!*** refers to a condition that can lead to damage or malfunction of the equipment.

WARNING!

Electrical shock hazard:

When operated by ac power, the monitor must only be connected to a grounded (3-wire) supply. Ensure power and protective ground lines are connected correctly.

When the monitor is operated by an external battery which is connected to a battery recharging device, this device must be medical grade (double isolation).

If any power supply or earthing arrangement is suspect, power the monitor only from its internal or from an external battery.

Maintenance requiring removal of the case or covers must not be attempted by the operator, but must be referred to linde medical sensors trained service personnel.

The use of accessories, sensors and cables other than those specified, with the exception of sensors and cables sold by the manufacturer of the MicroGas 7650 system as replacement parts, may result in increased emissions or decreased immunity of the MicroGas 7650 system

Before cleaning the monitor, always switch it off and disconnect it from the ac mains power supply.

Keep plugs and connectors meticulously clean and dry, do not allow any liquid to enter the equipment.

The MicroGas 7650 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the MicroGas 7650 should be observed to verify normal operation in the configuration in which it will be used.

Pins of connectors identified with this esd warning symbol **should not be touched and connections should not be made to these connectors unless esd precautionary procedures described in the section 2.19 of this document are used.**

When connecting other equipment to MicroGas 7650, consult the manufacturer of that equipment or a qualified engineer to ensure that the safety of the patient, the operator or the environment will not be impaired, connections must only be made to equipment complying with en 60601-1. All combinations of equipment must be in compliance with iec/en 60601-1-1 standard system requirements.

Explosion and flammability hazards:

Never operate the monitor in the presence of flammable anaesthetics or other flammable substances, or in an environment which has increased oxygen concentration.

Patient injury hazard:

Prolonged exposure of the heated sensor may cause a skin burn, the recommendations on sensor temperature and exposure time given in the operating manual should be read carefully before using the instrument on a patient.

Patient safety and perfomance of this unit when connected to patients under-going magnetic resonance diagnostic procedures are unknown, we advise that all sensors and cables used on this unit are removed from patient during such procedures

Failure of operation:

If the monitor fails to operate as described, do not use it until the problem has been corrected by Linde Medical Sensors trained service personnel.

Alarm-off mode:

If the alarm functions have been turned off, i.e. the alarm-off indicator is lit, no alarm will sound if a PO_2 or PCO_2 value exceeds one of the preset alarm limits. Therefore, the alarm-off mode should not be used in situations where its use could compromise patient safety.

CAUTION!

To clean the monitor and the sensor follow the instructions given in this manual. Do not use any abrasive agent or any chemical that is not recommended in this manual.

Do not expose the monitor to high humidity or heat (for details see section 2.13).

Certain types of mobile telecommunications equipment could potentially interfere with equipment operation. Mobile telecommunication equipment should not be used within five meters of patient monitoring equipment.

Equipment is protected against defibrillator discharge. Parameter displays may be temporarily affected during defibrillation, but will rapidly recover.

When this equipment is used with a defibrillator, the user must precisely follow the instructions in the defibrillator operating manual.

To ensure protection of patient, operator and equipment from the effects of the defibrillation and diathermy/electrosurgery, cables manufactured by Linde Medical Sensors must be used.

Equipment is protected against electrostatic discharge. The PCO_2 display may be temporarly affected during discharge to chassis ground but will rapidly recover.

For use during electrosurgery the monitor, sensor and their cables are to be physically separated from the electrosurgical equipment. The sensor must not be placed in the electrical pathway between cutting and counter electrode. Electrosurgery will produce, at most, a minimal transient disturbance in the reading and it will not affect the system calibration.

If any function fails to operate correctly consult a Linde Medical Sensors trained service personnel.

Where the equipment has been wetted accidentally, it should be wiped dry externally and allowed to dry thoroughly before use.

This unit needs special precautions regarding EMC and needs to be installed and put into service according to the emc information provided in the section 2.15 of this document.

1 General Information

1.1 Introduction

Linde Medical Sensors MicroGas 7650 is a blood gas monitor equipped with an integrated calibrator. The device provides reliable, continuous measurement of transcutaneous oxygen and carbon dioxide tensions by using a combined PO_2/PCO_2 sensor (type COMBI•M). The sensor is calibrated fully automatically when it is placed into the built-in calibration chamber. When not in use, the sensor is stored within the calibration chamber and the system is ready to use at any time. The monitor detects and gives warning when the oxygen and/or the carbon dioxide tensions exceeds the alarm limits, the values of which are adjustable by the operator. Fault conditions are indicated and routine operating messages are also displayed. Power is supplied from AC mains or the internal rechargeable battery or an external battery.

1.2 Principle of Operation

Since oxygen and carbon dioxide gases are able to diffuse through the body tissue and skin, it is possible to detect them by means of a sensor applied to the skin surface. In order to create local arterialization, the sensor is heated to a constant temperature which is higher than normal body surface temperature.

In the COMBI•M sensor, the basic elements of a Clark-type PO_2 sensor and a Severinghaus-type PCO_2 sensor are combined. Oxygen is measured amperometrically by reduction at a platinum microcathode which is negatively polarized with respect to an Ag/AgCl reference electrode. The current measured is proportional to the oxygen partial pressure. Carbon dioxide is measured potentiometrically by determining the Ph of an electrolyte. A change of Ph is proportional to the logarithm of a PCO_2 change. The Ph is determined by measuring the potential between a miniaturized Ph glass electrode and an Ag/AgCl reference electrode. The same Ag/AgCl electrode is used for both measuring functions. The electrolyte is provided within a hydrophillic spacer which is placed on top of the sensing area. The spacer is covered by a highly gas permeable, hydrophobic membrane.

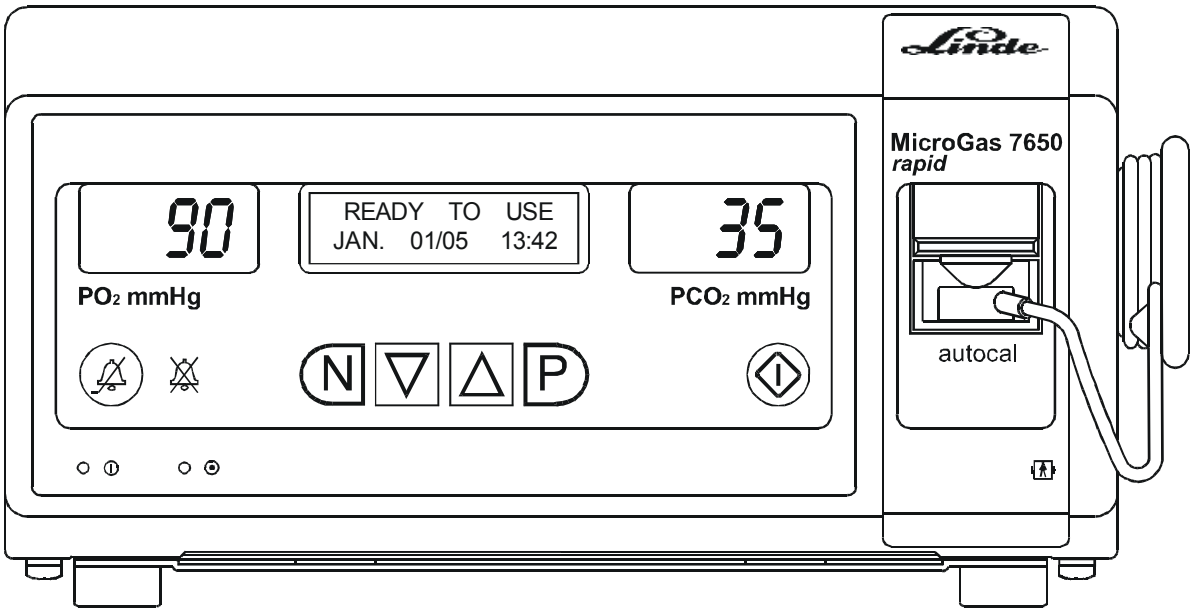
The COMBI•M sensor used with MicroGas 7650 differs from the previous sensor type "COMBI" by three important improvements:

- The preparation of the Combi•M sensor is performed by a new simplified technique with the aid of a one-step sensor preparator with integrated spacer, membrane and membrane retainer ring.
- The surface of the COMBI•M sensor is covered by a thin plate perforated at the positions of the three electrodes. This plate provides an efficient protection of the sensitive membrane from mechanical damage.
- The COMBI•M sensor contains a memory which allows the storage of the calibration values and of other relevant sensor data. By evaluating these data in the monitor, any irregularity of the sensor characteristics or the necessity of a new sensor preparation can be detected at an early stage. In addition, the built-in memory allows the user to change the sensor from one monitor to the other without the need of a recalibration.

The transcutaneous blood gas value has to be interpreted primarily as the blood gas partial pressure prevailing at the level of the arterialized skin tissue. In general, this value correlates well with the corresponding arterial blood gas partial pressure.

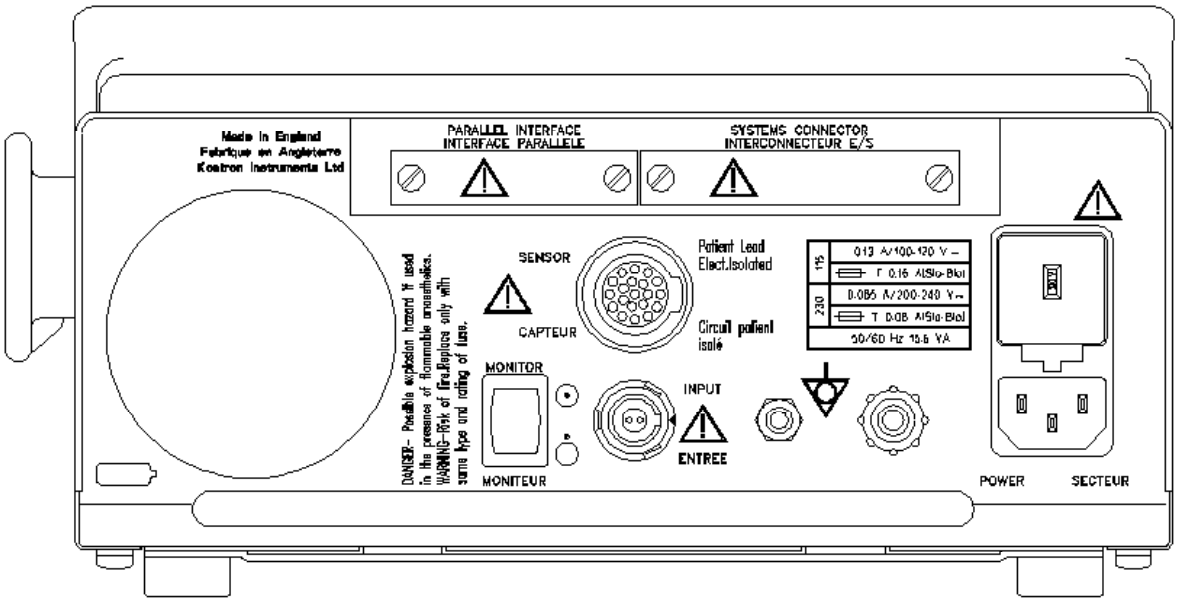
1.3 Controls, Indicators and Connectors

1.3.1 Front panel



Left window	LED-display indicating PO_2 values between 0 and 999 mmHg (0 and 99.9 kPa) in steps of 1 mmHg (0.1 kPa) or - - - when PO_2 display is switched off.
Middle window	Illuminated LCD display showing parameter settings and operator messages.
Right window	LED display indicating PCO_2 values between 1 and 200 mmHg (0.1 and 20.0 kPa) in steps of 1 mmHg (0.1 kPa).
⏀	"Line connected and internal battery charging" indicator lamp
⦿	"Monitor on" indicator lamp
🔕	"Alarm mute/off" key, is used either to mute the alarm tone if an alarm condition is indicated or to switch alarm detection facilities off.
🔕	"Alarm off" indicator lamp, illuminates when alarms are turned off or alarm tone is muted.
P	"Parameter" key is used to select all monitor and sensor parameters
▽ △	"Down/Up" keys, used to alter the selected parameter settings. When pressing one of these keys in the "ready to use" mode, the PO_2/PCO_2 displays are activated.
N	"Normal parameter" key, is used to activate or to alter the memorized normal parameter settings which may be selected individually by the operator.
⏻	"Start monitoring" key. Upon pressing this key, the site time clock is started at the preset measuring time and the remaining measuring duration is displayed. Five minutes later, the alarm detection facilities of the PO_2 and PCO_2 limits are activated. By pressing this key for 2 seconds a calibration is activated when the sensor is placed in the calibration chamber. The PO_2 and the PCO_2 values are displayed during the calibration process.
autocal	Calibration chamber for COMBI•M sensor, is also used for storing the sensor in the "ready to use" mode.
	Symbol of type BF equipment, defibrillator proof (EN 60601-1)

1.3.2 Rear panel



POWER	AC power compartment, containing line cord plug, fuses and voltage selector.
MONITOR	Monitor on/off switch
SENSOR	Sensor input socket
	Connectors for equipotential ground
	Equipotential ground connector adjacent to this symbol
INPUT	Connector for external 12-24V battery
	Attention, before using the connector adjacent to this symbol the instructions given in the operating manual must be read.
	Physiological effects (Sensor Connection) Note that the sensor has a heated surface. Please operate strictly in accordance with section 1.4.2 of the operating manual.
PARALLEL INTERFACE	Connector for printer interface.
SYSTEMS CONNECTOR	Connector for Linde Medical Sensors systems interface, including RS423, analog output and status data output.
	Container with screw connector for Linde Medical Sensors gas cylinders (CAL-Gas).

1.3.3 Underneath base

- CAUTION and ATTENTION Label
- CE-Label
- Label indicating service status of instrument and label indicating software revision status of instrument (both for Linde Medical Sensors trained service personnel).
- Speaker

2 Specification

2.1 IEC Equipment Classification

Power source

Either by AC line voltages of 200-240V (±10%) and 100-120V (±10%), 50/60Hz, or by internal rechargeable battery, or by an external battery 12V-24V.

Electrical Safety (EN 60601-1)

Protection against electrical shock:

- Class I: when connected to AC line voltage 100-120 Vrms or 200-240 Vrms
- Class II: when connected to external Battery

Internally Powered Equipment: when supplied by the internal battery

Patient leakage current: Type BF

- at 200-240 Vrms: <20μA
- at 100-120 Vrms: <10μA

Protected against the effect of defibrillation

Protection against ingress of liquids

Not protected

Mode of operation

Suitable for continuous operation

Degree of mobility

Transportable

Degree of protection against hazards of explosions

Not protected - not suitable for use with flammable gases.

Electromagnetic compatibility (EMC)

The equipment complies with IEC 60601-1-2 (2001) and the relevant standards for emission and immunity, see section 2.15, Electromagnetic Compatibility Declaration.

2.2 Inputs

2.2.1 Monitor

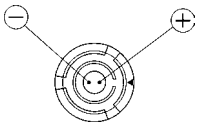
Mains supply

3 way mains input plug (rear panel)

Input DC supply

2 way socket (rear panel) for the connection to an external battery (12-24V)

Connector type: Redel SA, Type PAG-M02 GLAC GSG

Polarity: 

Sensor input

Nicolay, 20 way socket (rear panel)

2.2.2 Sensor Type COMBI•M

Clark-type PO_2 sensor combined with Stow-Severinghaus type PCO_2-Sensor, containing a heating resistor, two calibrated precision thermistors and two pre-amplifying circuits. All components are embedded in epoxy. One-step sensor preparation. Protection of sensor surface against mechanical damage.

- Sensor diameter: 20 mm
- Sensor height: 10 mm
- Cable: 2.8 m length, highly flexible, polyurethane coated
- Heated area: approx. 40 mm^2
- Skin temperature: approx. 1°C below selected sensor core temperature
- Temperature control and monitoring by 2 thermistors
- Heating resistor: 100 Ω
- Thermistor resistance, trimmed: 5600 Ω at 44 °C
- In Vitro response time, τ90%: < 25 sec for PO_2
  < 60 sec for PCO_2
- Drift (in CAL-Gas): < 1%/h for PO_2
  < 1%/h for PCO_2

Built-in memory (EEPROM) within sensor plug for:

- PO_2 and PCO_2 calibration values
- PO_2 zero current and PCO_2 slope
- Date and time of last calibration
- Date of last sensor preparation
- Date of last slope adjustment

Noise suppression

by two built-in preamplifiers

Operating time

two weeks at normal use between two preparations

Life time

Normal wear and tear will limit the lifetime of this sensor. However, provided the sensor and its cable are handled with care, a usable safe lifetime of four years may be expected. Harsh treatment will drastically reduce the lifetime of the sensor.

Interference by anaesthetic gases (in vitro)

	PO_2	PCO_2
75% N_2O	< 10 mmHg	negligible
2% Halothane	appr. 200 mmHg	negligible
2% Enflurane	negligible	negligible
2% Isoflurane	negligible	negligible

Note: The influence of halothane on the transcutaneous PO_2 value during in vivo monitoring is significantly less.

2.3 Controls

Front panel

- Start monitoring key
- Parameter key
- Down/Up keys
- Normal parameter key
- Alarm mute/off key

Rear panel

Monitor on /off switch

2.4 Outputs

Displays

- PO_2 display: 3 x 12.7mm high, 7 segments green LED
- PCO_2 display: 3 x 12.7mm high, 7 segments green LED
- Middle display: Dot matrix LCD, 2 x 16 characters (2 lines) module, LED backlight and adjustable viewing angle

Indicator lamps

- Line connected (yellow)
- Monitor on (green)
- Alarm off (yellow)

Loudspeaker

For audio signals, frequency 400 Hz

Systems Connector

1 x 37 way connector, carrying:

- analog outputs
- RS 423 digital interface
- status signals

Details see section 2.16

Parallel Interface

1 x 25 way connector, carrying:
- Centronics parallel interface
- Outputs for printer

Note: Only equipment complying with IEC 601-1 may be connected.

2.5 Calibrator

Built-in one gas calibrator

Control of gas pressure and gas flow to the calibration chamber during calibration.

CAL-Gas cylinder

Composition: 12.0% 0_2, 7.0% CO_2, rest N_2

Volume: nominal 0.5 litre

Filling pressure: 10.8 bar at 21°C

Typical function time (at 6 calibrations per day): conventional → 1 month, rapid type → 2 months

2.6 Performance

PO_2

0 to 999 mmHg (0 to 99.9 kPa) or --- when PO_2 display is switched off

PCO_2

1 to 200 mmHg (0.1 to 20.0 kPa), Resolution: 1 mmHg (0.1 kPa)

Heating

Sensor core temperature selectable between 37°C and 45°C in steps of 0.5°C

Accuracy of selection ± 0.2°C

Display of actual temperature flashing during $\Delta T > 0.3°C$

Site timer

Timer counting down from an adjustable starting value during measurement and triggering an alarm when selected measuring time has elapsed.

Site time adjustable between ½ and 24 hours in steps of ½ hour and step above 24:00 = infinite (display --:--).

2.7 Alarms

PO_2

	Minimum	Maximum	Default
low	0 mmHg (0.0 kPa)	99 mmHg (13.2 kPa)	50 mmHg (6.7 kPa)
high	5 mmHg (0.7 kPa)	999 mmHg (133.2 kPa)	100 mmHg (13.3 kPa)
	(--- when PO_2 display switched off)		

Low limit to high limit separation is 5 mmHg (1.0 kPa)

PCO_2

	Minimum	Maximum	Default
low	0 mmHg (0.0 kPa)	99 mmHg (13.2 kPa)	25 mmHg (3.3 kPa)
high	5 mmHg (0.7 kPa)	200 mmHg (25.0 kPa)	50 mmHg (6.7 kPa)

Low limit to high limit separation is 5 mmHg (1.0 kPa)

2.8 Alarm Indications

Messages

TOO HIGH PO2
95 ALARM LIMIT

TOO LOW PO2
40 ALARM LIMIT

TOO HIGH PCO2
ALARM LIMIT 45

TOO LOW PCO2
ALARM LIMIT 25

Audible Indication

Three short tones repeating every two seconds

2.9 Fault Indications

The monitor is capable of detecting various fault conditions. In such case, a message describing the fault is displayed. Simultaneously (or in certain cases with a 5 minutes delay), an alarm sounds consisting of a single long tone, repeated every 1½ seconds. The following fault messages may appear:

CONNECT SENSOR	The monitor has detected that no sensor is connected. This fault message is reset after a sensor has been connected.
SENSOR FAULT ALARM	Automatic shut down of heating in case of sensor fault. Triggered by one of the following conditions: • actual temp. > set temp. + 1°C for 4 sec • actual temp. < set temp. - 1°C for t_{max} (maximum time) t_{max} is normally 30 sec but 5 min during warming up of the sensor • (actual temp.- set temp.) > 0.3°C for t_{max} • difference between thermistors > 0.6°C for 4 sec • difference between thermistors > 0.3°C for t_{max}
MONITOR FAULT 04	Automatic shut down of the floating board supply voltage. The monitor has detected an irregularity of one of its functions. If this message cannot be reset by switching the monitor off and on again, the number should be noted and a trained service technician has to be consulted. If the monitor can be restarted, all settings have to be checked and readjusted if necessary.
NO GAS FLOW RENEW GAS BOTTLE	This message appears when the gas cylinder installed in the monitor is empty or when no gas cylinder is fitted.
GAS FLOW DISTURBED F1/F2	If one of these messages appears during a calibration, the monitor has detected an irregularity of the pressure control system. In such case, a Linde Medical Sensors trained service technician has to be consulted.
CHARGE BATTERY MINIMUM 12 H alternating with: CONNECT UNIT TO MAINS POWER	The internal battery needs to be recharged. The monitor must therefore be connected to AC power within a few minutes after appearance of this message. The minimum charging time required is 12 hours. *Note: In case the internal battery has been discharged below a critical level the displays are no more activated. After connecting the monitor to AC power it is necessary to switch the monitor (→Off →On) to reactivate them.*
SITE TIME ELAPSED	This message appears when the preset time limit of a monitoring period has been passed. The sensor has to be removed from the application site in this case.
The two fault messages described below are accompanied by the acoustic signal only if the fault situation persists for more than 5 minutes:	
PLACE SENSOR IN CAL. CHAMBER	The monitor has detected that the sensor is exposed for too long (appr. 2 to 3 minutes) to air. When the sensor is not in use it must always be stored in the calibration chamber.
PRESS START MONITORING alternating with the main parameters such as: 95 44.0 45 50 4:00 25	This display appears each time the sensor is removed from the calibration chamber in the "ready to use" mode. After the sensor has been attached to the patient subsequently, the ⏎ key should be pushed. If this is not done, the fault alarm tone will sound after 5 minutes.

2.10 Other Messages

Beside the alarm and fault messages and beside N- and P- key messages (not described in this manual) the following status indications are displayed.

7650 SYSTEM TEST	Appears shortly after the monitor has been switched on and identifies the system self-check.
7650 REV. 12.00 followed by: FLOAT REV. 4.00	Appears at the end of the initial self-check period to identify the software revision status of the monitor. (Revision numbers are examples)
UPDATE SOFTWARE	Upon appearance of this message, a trained service technician has to be consulted.
UPDATE SENSOR	Appears if a sensor type is connected which is not compatible with MicroGas 7650 (for example, type COMBI instead of COMBI•M).
CALIBRATE SENSOR	The monitor has detected a condition requiring a calibration of the sensor (for example, after a new preparation). The sensor has to be inserted into the calibration chamber. This message appears also when switching the monitor on or when connecting the sensor to the monitor.
REMEMBRANE SENSOR	This message appears when more than 14 days have elapsed since the last sensor preparation, or if the monitor has detected an irregularity of the sensor performance during a calibration.
REPEATING CALIBRATION	If the PO_2 and/or PCO_2 values are not stable within 10 minutes after the start of a calibration, the calibration is repeated once as indicated by this message and the displays of the PO_2 and PCO_2 values are turned on.
CALIBRATE SENSOR alternating with the main parameters such as: 95 44.0 45 50 3:56 25	This message appears when the sensor temperature has been changed during a monitoring period by more than 2°C or when more than 24 hours have elapsed since the last calibration.
RENEW GAS BOTTLE ▮▮▮▮	Appears when the pressure within the gas cylinder is below 1 bar. The number of fields ▮ indicates the remaining gas volume. One ▮ corresponds approximately to one calibration. If the monitor is switched off and on again during this status or if the gas cylinder is accidentally replaced by another one with a pressure of less than one bar, the message RENEW GAS BOTTLE will appear again, however, without the ▮ indicator-fields.
36 MIN SITE TIME Remaining	This messages appears at the end of a monitoring period when only 10% of the preset monitoring duration (maximum one hour) is remaining.
▲	Triangle indicators ▲ appear side to the PCO_2 and/or PO_2 alarm limit values if an in vivo PCO_2 and/or PO_2 correction is applied (see section 3.3.4, P2-9 and P2-10 of the Operating Manual). 95▲44.0▲45 50▲3:56▲25
PRINTER FAULT	This message appears after pressing the [P] key continuously for 4 seconds (selection of printer mode) if: • the printer or the interface is defective • the printer is not connected to AC power or not switched on • no printer is connected to MicroGas 7650 • there is no recording paper in the printer

2.11 Power Supply and Earthing

Mains power supply

200 to 240 Vrms, ±10%, 50/60 Hz or 100 to 120 Vrms, ±10%, 50/60 Hz

Mains voltage range can be set externally (see section 4.3)

Power consumption

Max. 15.6VA

Fuses (rear panel)

Two 5 x 20mm, type T (Slo-Blo):

- 80mA, for 200 to 240 Vrms mains
- 160mA, for 100 to 120 Vrms mains

External battery

12V to 24V, ±10%

WARNING!

If the external battery is connected to a battery recharging device, this device must be medical grade (double isolation).

Internal battery

Lead acid cell: 12V/1.8Ah, rechargeable

Charging time: 18 hours (12 hours minimum)

Operating time on battery: 30 to 120 minutes, depending on the mode of operation of the monitor and the age of the battery.

To keep the charging state of the internal battery at maximum leave the monitor connected to AC power. In case the system should not be connected to AC power for an extended period of time (several months) it is recommended to disconnect the battery. As this requires the removal of the outer case, this must be performed only by a Linde Medical Sensors trained technician.

Earthing

Earth connection via mains connector and equipotential earth (ground) terminal on rear panel.

All exposed metal parts are earthed.

Earth leakage: <100 μA

2.12 External Features

Dimensions shown do not include sensor and power cable, but includes the sensor spool.

Size

135mm (5.3 inches) high

300mm (11.8 inches) deep

266mm (10.5 inches) wide

Weight

5,6kg (12.3 lbs) including gas cylinder, without sensor and power cord.

Case

Wipe clean cover and front panel

2.13 Environmental Operating Conditions

Temperature

+15°C to +40°C (+59°F to +104°F)

Relative humidity

< 90% non-condensing

Ambient pressure

450 to 800 mmHg (600 to 1060 hPa)

2.14 Environmental Transport and Storage Conditions

(in original factory packaging)

Temperature

-20°C to 60°C

Relative Humidity

10% to 95%

Ambient pressure

375 to 800 mmHg (500 to 1060 hPa)

2.15 Electromagnetic Compatibility Declaration

WARNING!

The use of accessories, sensors and cables other than those specified, with the exception of sensors and cables sold by the manufacturer of the MicroGas 7650 as replacement parts, may result in increased emissions or decreased immunity of the MicroGas 7650.

2.15.1 Electromagnetic Emissions

The MicroGas 7650 is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroGas 7650 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Groupe 1	The MicroGas 7650 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MicroGas 7650 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

2.15.2 Electromagnetic Immunity

The MicroGas 7650 is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroGas 7650 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ± 2 kV common mode	±1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroGas 7650 requires continued operation during power mains interruptions, it is recommended that the MicroGas 7650 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

2.15.3 Electromagnetic Immunity, RF portable equipment

The MicroGas 7650 is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroGas 7650 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the MicroGas 7650, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:			

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MicroGas 7650 is used exceeds the applicable RF compliance level above, the MicroGas 7650 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MicroGas 7650.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

2.15.4 Recommended separation distances

The MicroGas 7650 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MicroGas 7650 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MicroGas 7650 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.15.5 Cables length

WARNING!

The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the MicroGas 7650.

Cables and sensor	Maximum length	Complies with
COMBI•M sensor Type 82 (part no 060 5000)	3 m	RF emissions, CISPR 11, Class B/Group 1 Harmonic emissions, IEC 61000-3-2 Voltage fluctuations/flicker emission, IEC 61000-3-3 Electrostatic discharge (ESD), IEC 61000-4-2 Electric fast transient/burst, IEC 61000-4-4 Surge, IEC 61000-4-5 Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Conducted RF IEC 61000-4-6 Radiated RF, IEC 61000-4-3
MicroGas - PC Interface Cable (part no 7650 0081)	2 m	
MicroGas - VueLink Adapter Cable (part no 7650 0080)	0.5 m	
PHILIPS-VueLink Interface Cable (25 pin "D" to 10 pin Philips, shielded)	2 m	
Printer Cable (25 pin "D" to 36 pin Centronics, shielded)	2 m	

2.16 Communication Interface (Systems Connector)

2.16.1 Overview

Patient data can be obtained mainly through the serial interface and analog outputs of the "Systems Connector" on the back of the MicroGas monitor by connecting it to an attached Personal Computer (PC) or a Component Multiparameter System (CMS).

When connecting the MicroGas monitor to a PC or CMS, verify proper operation before clinical use. Both the MicroGas monitor and the PC or CMS must be connected to a grounded AC outlet. The communication protocol setting must be set as described in section 3.3 "Adjustment of parameters" on second parameter level P2-15, of the MicroGas Operating Manual.

Any PC or non-medical device connected to the "Systems Connector" must be certified according to IEC/EN 60950 Standard. All combinations of equipment must be in compliance with IEC/EN 60601-1-1 Standard systems requirements. Anyone who connects a PC or a CMS to the MicroGas "Systems Connector" configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC/EN 60601-1-1 and the electromagnetic compatibility system standard IEC/EN 60601-1-2.

2.16.2 Connecting to the Systems Connector

The MicroGas "Systems Connector" may be connected to the PC or CMS by using a cable terminated with a shielded DB-37 connector. The cable should be no more than 2m in length.

The cable used must have a braided shield providing 100% coverage. The shield must have a 360-degree connection to the metal shell on the DB-37 connector and to the connector on the PC or CMS. Do not create sharp bends in the cable, as this may tear or break the shielding.

See connection details in section 2.16.5 for EasyLink, section 2.16.6 for VueLink and section 2.16.7 for MonLink.

2.16.3 Systems Connector pinouts

pin no.	description
1	0V
2	RxD, RS423
3	TxD, RS423
4	RTS, RS423
5	CTS, RS423
6	not used
7	not used
8	0V
9	auxillary supply voltage 10 to 26 V, Imax = 300 mA
10	0V
11	PO_2 analog output, 0-6 V = 0-300 mmHg
12	PCO_2 analog output, 0-6 V = 0-300 mmHg
13	0V
14	0V
15	0V
16 to 19	not used
20	status signal ALARM ON, Open Collector, active low, I_{sink} = 10 mA, U_{source} = 15 V
21	status signal ALARM RESET, Open Collector, active low, I_{sink} = 10 mA, U_{source} = 15 V
22	status signal ALARM, Open Collector, active low, I_{sink} = 10 mA, U_{source} = 15 V
23	status signal FAULT, Open Collector, active low, I_{sink} = 10 mA, U_{source} = 15 V
24	not used
25	not used
26	status signal MONITOR ON, Open Collector, active low, I_{sink} = 10 mA, U_{source} = 15 V
27	0V
28	0V
29	0V
30	PO_2 analog output, 0-6 V = 0-300 mmHg
31	PCO_2 analog output, 0-6 V = 0-300 mmHg
32 to 34	0V
35 to 37	not used

2.16.4 Communication protocol

Through the Parameters Adjustment menu (see Operating Manual section 3.3.4 P2-15), the following communication protocols are available on the serial interface:

EasyLink

Unconditionally real-time data transmission. Memory dump / download functions can be request from the host device (PC or CMS)

Note: only since Main Software Rev. 12.00

VueLink

Compatible with the Philips VueLink Open Interface.

Note: only since Main Software Rev. 12.00

MonLink

Transmission of real-time data on host request. The protocol corresponds to the communication protocol of previous software versions of MicroGas 7650 monitors.

These three possibilities are detailed below:

2.16.5 EasyLink

Easy operation

When the EasyLink communication protocol is set, the MicroGas monitor sends automatically real-time data. The data format used is ASCII CSV (Coma Separated Values) which simplify the treatment of data by the PC or CMS host device.

Easy connection

To connect the PC or CMS to the MicroGas "Systems Connector", you need only a 3 wire shielded cable.

Example of connection to a PC serial COM port:

MicroGas DB-37		PC DB-9
pin 2 (RxD)	----------	pin 3 (TXD)
pin 3 (TxD)	----------	pin 2 (RxD)
pin 27 (GND)	----------	pin 5 (GND)
pin 28 (GND)	--shielding--	pin 5 (GND)

Principle

Real-time data is continuously sent to the serial port. A new line of data is send every second. Column heading line will be send after every 60 data lines, or if one of the values in the column heading changes.

Serial port settings

Baud rate of 4800, 8 bit data, even parity, 1 stop bit, without handshaking.

Memory dump/download

The host device can request a memory dump/download of the last 18H patient data. Also, the results can be downloaded to a printer or to a personal computer (PC). The monitor automatically stores the measured patient data over the last 18 hours using the FIFO (First In, First Out) principle. Data are stored whenever values are displayed e.g. during patient monitoring. The memory will indicate zero values for those time intervals in which no values are displayed e.g. while the sensor is placed in the calibration/storage chamber or while the monitor is turned off. The monitor should be turned on to keep the memory active.

1. Heading and data lines content of real-time data output:

	Head bytes	**Data bytes**	**Content**	**Description**
Column pos. 1:				**Date and time**
Heading line:	12		**$<date>,** $2002.30.07,	Date of the next data line, format "yyyy.mm.dd"
Data line:		9	**<time>,** 11:22:33,	Time of the actual data line, format "hh:mm:ss"
Column pos. 2:				**PCO2 value**
Heading line:	20		**PCO2[<unit>]<limit>,** PCO2[mmHg]0012:0123, PCO2[kPa_]01.2:12.3,	Indication of the PCO2 unit in "mmHg" or "kPa_" and alarm limits "low:high" valid for the next data lines.
Data line:		5	**<value>,** 0123, 23.4, --.-,	PCO2 value in "mmHg" without decimal point or in "kPa" with decimal point. Indication of "----" or "--.-" if no value is available or is out of range.
Column pos. 3:				**PCO2 alarm status**
Heading line:	6		**PCO2s,**	No heading parameter
Data line:		2	**<code>,** N, A, S,	Possible codes are: "N" no Alarm "A" alarm active "S" alarm silenced, reset
Column pos. 4:				**PO2 value**
Heading line:	14		**PO2[<unit>]<limit>,** PO2[mmHg]0010:0100, PO2[kPa_]01.0:10.0,	Indication of the PO2 alarm limits low:high" valid for the next data lines.
Data line:		4	**<value>,** 0100, 10.0, ----, --.-,	Indication of "----" if no value is available.
Column pos. 5:				**PO2 alarm status**
Heading line:	6		**PO2s,**	No heading parameter
Data line:		2	**<code>,** N, A, S,	Possible codes are: "N" no Alarm "A" alarm active "S" alarm silenced, reset
Column pos. 6:				**Sensor temperature**
Heading line:	12		**Temp[C]<set>,** Temp[C]44.0,	Indication of the temperature set valid for the next data lines.
Data line:		5	**<value>,** 41.9,	Indication of "--.-" if no value is available.
Column pos. 7:				**Site timer**
Heading line:	6		**Timer,**	No heading parameter
Data line:		6	<**timer>,** 02:15,	Site time left of the actual data line, format "hh:mm"

	Head bytes	Data bytes	Content	Description
Column pos. 8:				**Mode**
Heading line:	5		**Mode,** Mode,	No heading parameter
Data line:		2	**<mode>,** C, R, P, M,	Possible modes are: "C" calibrating "R" ready to use "P" pre-measurement "M" measurement "?" other (connect sensor, monitor fault)
Column pos. 9:				**General status**
Heading line:	8		**Status<cr><lf>** Status	No heading parameter This is the last column of the heading line, ending with "cr lf" (0x0D 0x0A) bytes.
Data line:		3	**<code><cr><lf>** N A S O	Possible codes are: "N" no alarm "A" at least one alarm active "S" at least one alarm silenced "O" alarm switched off This is the last column of the data line, ending with "cr lf" (0x0D 0x0A) bytes.
Total bytes per line	**93**	**39**		

(Expected recordable data + heading length: ~3.5 MB/day)

Column headings line example:

"$2002.07.31,PCO2[mmHg]0025:0050,PCO2N,PO2[mmHg]0050:0100,PO2N,Temp[C]44.0,Timer,Mode,Status"

Data line example:

"11:22:33,0040,N,0100,N,43.9,04:00,R,N"

2. Memory dump (18 hours memory):

Memory dump request/stop sequence:

When EasyLink is selected the host can request a memory dump.

To request a memory dump, the following ASCII sequence must be send to the MicroGas Monitor:

MD<cr><lf> (4 bytes)

The EasyLink real time data output is interrupted and the memory dump starts.

After the memory dump is finished the monitor returns to the EasyLink real time data output.

Sending the memory dump request when a memory dump is still in progress will stop the memory dump and return to the real time data output.

Memory dump response:

The memory dump response is organized as follows:

- 2160 data lines (2 data lines per minute for 18 hours)
- start of a data line = **'$'**
- end of data line = **<CR>, <LF>**
- memory dump closing byte = **0FE**

One data line represents 30 seconds of memorized values and consists of the following 15, comma separated values (ASCII CSV):

	1.	Year.Month.Day	10 byte ASCII (incl. 2 '.')
	2.	Hour:Minute:Second	8 byte ASCII (incl. 2 ':')
*	3.	PO2 value	3 byte ASCII
*	4.	PCO2 value	3 byte ASCII
*	5.	PO2 low alarm limit	3 byte ASCII
*	6.	PO2 high alarm limit	3 byte ASCII
*	7.	PCO2 low alarm limit	3 byte ASCII
*	8.	PCO2 high alarm limit	3 byte ASCII
	9.	Set sensor temperature	4 byte ASCII (incl. dec. point)
	10.	PO2 in vivo correction factor	4 byte ASCII (incl. dec. point)
	11.	PCO2 temperature correction	4 byte ASCII (incl. dec. point)
*	12.	PCO2 in vivo correction	3 byte ASCII
	13.	Status flag (10 bit)	5 byte ASCII (integer value in ASCII)
*	14.	PO2 calibration value	3 byte ASCII
*	15.	PCO2 correction value	3 byte ASCII

* = units are in mmHg if status flag bit 10 = 0 or in kPa/10 if status flag bit 10 = 1

Total length of one data line = 79 bytes (62 ASCII bytes, 14 commas, 1 start data line byte, 2 end data line bytes)

Expected down load time at 4800 baud: approx. 6½ minutes

Description of status flags:

Integer as 5 byte ASCII value

bit	value	description
0	1	Alarm On
1	2	Calibration
2	4	Calibration terminated
3	8	Site time elapsed alarm
4	16	Range x 4
5	32	Sensor fault
6	64	Remembrane sensor
7	128	In vivo PCO_2 correction Off
8	256	Gas flow ok
9	512	In vivo PO_2 correction Off
10	1024	PO_2 Off
11	2048	Monitor Fault
12	4096	units = kPa
13 - 15		not used

2.16.6 VueLink

As part of a Philips Patient Monitoring Systems (Philips V24/26, Philips CMS and Philips IntelliVue, here after called "Philips Monitor"), the MicroGas monitor is compatible with the following VueLink Open Interface module:

Module type

Philips VueLink module M1032A #A05 #K6B (type B, Auxiliary-plus, with Open Interface cable).

Ordering information:

- M1032A #A05 VueLink Open Interface Module (type B, auxiliary-plus)
- M1032A #K6B VueLink Open Interface Cable, 4m, Standard 25 pin male connector

Connection

Connect the VueLink module to the MicroGas Systems Connector with the VueLink Open Interface cable and the MicroGas-VueLink adapter cable (Part No 7650 0081)

Operation

When the VueLink protocol is selected (see Op. Man. section 3.3 P2-15), the VueLink module plugged in to the Philips Monitor Module device will automatically recognize the MicroGas 7650 monitor and will appear as “7650” on the VueLink module setup menu.

See section “VueLink” of the Philips Monitor documentation for setting and configuration of the VueLink module.

1. Available data:

The following real-time data are available on the Philips Monitor through the VueLink Interface:

Numeric values and settings

Philips Monitor Label	description
“$TcpCO_2$”	PCO_2 with alarm state
“$TcpO_2$”	PO_2 with alarm state
“Temp”	Sensor temperature
“TemSet”	Sensor temperature set
“Timer”	Site time remaining (format “hh.mm”)
“TimSet”	Site time set (format “hh.mm”)

Wave forms

Philips Monitor Label	aligned value	description
“$TcpCO_2$”	“$TcpCO_2$”	PCO_2 analog value
“$TcpO_2$”	“$TcpO_2$”	PO_2 analog value

2. Messages:

Alarm messages

Philips Monitor alarm	corresponding text
“7650 PO2 LOW”	"TOO LOW PO2"
“7650 PCO2 HIGH”	"TOO HIGH PCO2"
“7650 PCO2 LOW”	"TOO LOW PCO2"
“7650 PO2 HIGH”	"TOO HIGH PO2"

Note: The following alarm philosophy is used on the Philips Monitor with the MicroGas 7650 VueLink Module:

The alarm messages described above are “yellow” priority alarms.

The alarm signals are indicated on the display of the Philips Monitor by an alarm message on the center of the upper line and by the blinking of the related measured value, if displayed.

The alarm signals disappear on the Philips Monitor if the related auditory alarm signals on the MicroGas 7650 monitor are silenced.

Only one of the alarm messages described above is displayed at time. If more than one alarm condition is present, only the alarm message with the highest priority is displayed.

INOP messages

Philips Monitor INOP	corresponding text
“7650 SENSOR FAULT”	"SENSOR FAULT"
“CONNECT 7650 SENS”	"CONNECT SENSOR"
“7650 MONITOR. OFF”	"MONITORING OFF"
“7650 SENSOR OFF”	"PLACE SENSOR IN CAL CHAMBER"
“7650 TIME ELAPSED”	"SITE TIME ELAPSED"
“7650 BATTERY LOW”	"CHARGE BATTERY MINIMUM 12H"
“CAL. 7650 SENSOR”	"CALIBRATE SENSOR"
"REMEMBRANE 7650 S"	"REMEMBRANE SENSOR"
“7650 NO GAS FLOW”	"NO GAS FLOW, RENEW GAS BOTTLE"

Note: The following INOP philosophy is used on the Philips Monitor with the VueLink Module:

An INOP message is indicated on the left of the upper line on the Philips Monitor display as long as the related visual message is displayed on the MicroGas 7650 monitor.

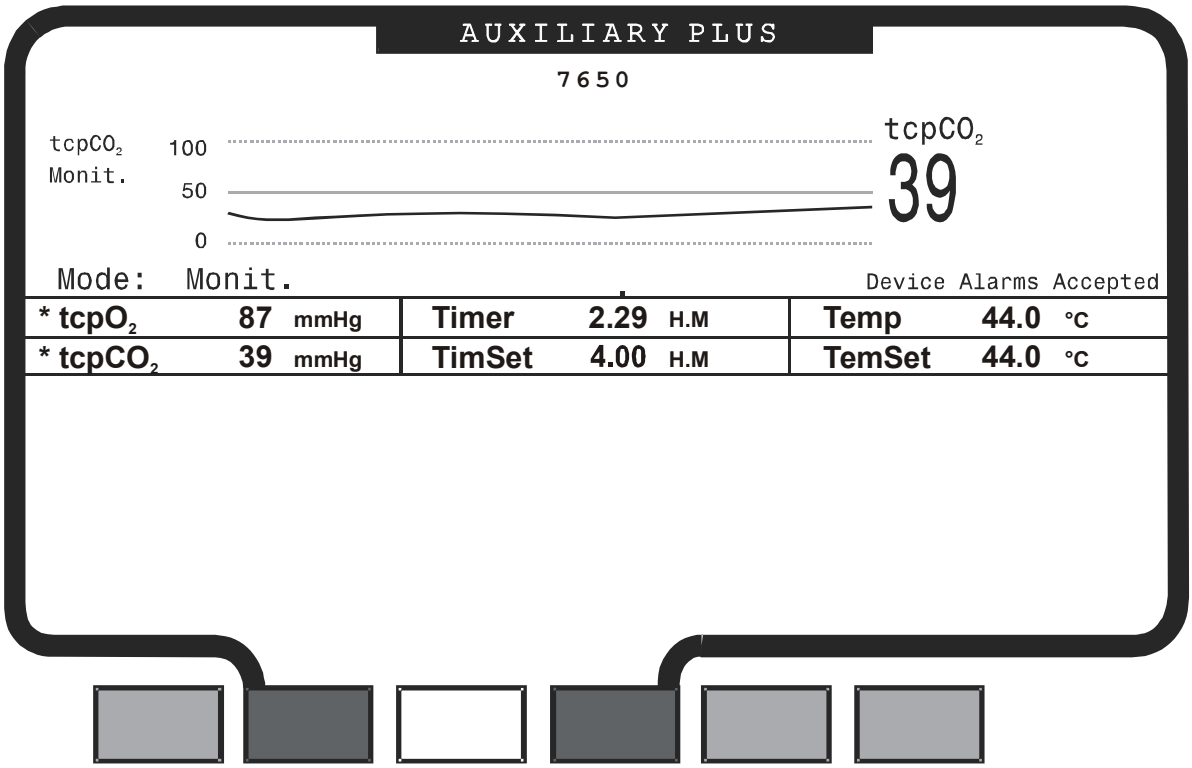
Only one of the INOP messages described above is displayed at time. If more than one INOP condition is present, only the INOP message with the highest priority is displayed.

Auditory alarms

The above described VueLink messages do not generate auditory signals on the Philips Monitor.

Philips Monitor mode	corresponding mode
“Calibr”	Calibrating sensor
“Ready”	Ready to use
“Applic”	Sensor application, monitoring not started
“Monit.”	Monitoring in progress

3. VueLink Task Window example:



2.16.7 MonLink

The MonLink correspond to the interface achitecture of previous software versions of MicroGas 7650 monitors. Therefore, it is compatible with existing devices.

Serial port configuration

Baud rate = 9,6 kBd, ASCII 7 bit, Parity even, 1 Stop bit, Pins 2, 3, 4, 5

Communication protocol

The monitor is always assumed to be "slave" in the sense that it cannot transmit information unless it has been requested to do so. The messages are always transmitted in "ASCII".

To initiate a communication the requesting device pulls RTS true and waits until the monitor replies with CTS true. Transmission can then proceed.

There are three different request codes possible which MicroGas 7650 can understand. The format of these codes and the corresponding replies are described below.

1. Request code no. 1 status, “Monitor status record":

Request format: `CRLF01$`

```
                          A
                          CF
Reply format: CRLFrr n1n2CRLF[00 >ON ND]CRLF$
                          N
```

Example:
```
00 00
[00 >N ND]
$
```

2. Request code no. 2 values, "Value and status record":

Request format: `CRLF02$`

```
                                    A
                                    F          kPa A
Reply format: CRLFrr n1n2CRLF00[PO2(Tc44.0_>1N_PO2=078mmHg>N]
                                    S              S

                           A
                           F           kPa A
CRLF00[PCO2(Tc44.0)_>2N_PCO2=043mmHg>N]CRLF$
                           S               S
```

Example:
```
00 00
00[PO2(Tc43.0)>2N_PO2=087mmHg>N]
00[PCO2(Tc43.0)>3N_PCO2=038mmHg>N]
$
```

3. Request code no. 3 limits, "Range and limits record":

Request format: `CRLF03$`

```
                                    A
                                    F
Reply format: CRLFrr n1n2CRLF00[PO2(Tc44.0)>1N_(0:50mmHg_1)_
                                    S
                                         A
              kPa                        F
PO2(050:100mmHg)]CRLF[PCO2(Tc44.0)>2N_
                                         S

      kPa                  kPa
(0:50mmHg_1)_PCO2(025:050mmHg)]CRLF$
```

Example:
```
00 00
00[PO2(Tc44.0)>2N_(0:50mmHg_1)_PO2(050:100mmHg)]
  [PCO2(Tc44.0)>3N_(0:50mmHg_1)_PCO2(25:50mmHg)]
$
```

4. Legend of codes:

CR	Carriage Return code (0x0D)
LF	Line Feed code (0x0A)
_	Space code (0x20)
rr	00 = Request message ok 01 = Request code not recognized 02 = Invalid specifier in request message 03 = Request message corrupt
n1n2	configuration code number of monitor between 00 and 99
00	Slot number (always 0)
PO2	Parameter 1 name
PCO2	Parameter 2 name
(Tc44.0)	Sensortemperature
1	PO2 is waveform 1
2	PCO2 is waveform 2
A	some parameter is in alarm
C	parameter in alarm and accepted
O	alarms have been switched off
N	normal operation
S	Standby and Calibration
F	Fault
ND	Normal Direct (real time data)
PO2=078mmHg/kPa	PO2 measurement value in mmHg or kPa
(0:50mmHg/kPa 1)	analog output, 50mmHg = 1V
PO2(50:100mmHg/kPa)	PO2 low and high alarm limits
$	End of message

2.16.8 Analog outputs

PO_2 analog output on pin 11 or 30:
0 to 6V = 0 to 300mmHg (20mV/mmHg) or 0 to 30.0kPa (20mV/0.1kPa)

PCO_2 analog output on pin 12 or 31:
0 to 6V = 0 to 300mmHg (20mV/mmHg) or 0 to 30.0kPa (20mV/0.1kPa)

2.17 Accessories

Sensor

060 5000	COMBI•M sensor Type 82

Accessories and disposables

060 5200	COMBI•M sensor supplies, consisting of: • 12 sensor preparators • one bottle COMBI sensor electrolyte

060 5300	Starter kit COMBI•M sensor including:
	• Application set, consisting of:
	  • dispenser for adhesive rings
	  • one roll of 250 pcs. adhesive rings Ø 32 mm
	  • one bottle contact gel
	• 3 sensor preparators
	• one bottle of COMBI sensor electrolyte

060 7110	Application set, consisting of: • dispenser for adhesive rings • one roll of 250 pcs. adhesive rings Ø32mm • one bottle contact gel
064 0210	CAL-Gas (box of 6 cylinders)
060 4210	COMBI sensor electrolyte (bottle of 10 ml)
060 3210	Contact gel (bottle of 10 ml)
060 3210.10	Contact gel (10 bottles of 10 ml)
060 7210	Adhesive rings (ext. diam. 32mm) for use with application set (4 rolls of 250 pcs. each)
060 7230	Adhesive rings (ext. diam. 20mm) for use with application set (4 rolls of 400 pcs. each)
7650 0080	MicroGas - VueLink Adapter Cable
7650 0081	MicroGas - PC Interface Cable

Manuals

7650 0910	Operating Manual, English
7650 0911	Operating Manual, German
7650 0914	Operating Manual, Italian
7650 0915	Operating Manual, French
7650 0916	Operating Manual, Spanish
7650 0901	Service Manual, English

2.18 Description of Warning Symbols

	Symbol of type BF equipment, defibrillator proof (EN 60601-1)
	Equipotential ground connector adjacent to this symbol
	Attention, before using the connector adjacent to this symbol the instructions given in the operating manual must be read.

2.19 ESD Precautionary Procedures

ESD warning symbol:

Accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a hand-held tool unless the proper precautionary procedures described below have been followed.

To prevent build up of electrostatic charge in the environment where the MicroGas is used, the following methods can be used if applicable: air conditioning, humidification, conductive floor coverings, non-synthetic clothing.

Before connecting the Combi•M sensor to the MicroGas, first touch the frame of the rear panel of the MicroGas with one hand and then connect the sensor with the other hand.

It is recommended that all users of the MicroGas receive an explanation of the ESD warning symbol and a training in ESD precautionary procedures.

The ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the MicroGas prior to making a connection.

3 Technical Description

Refer to Block Diagram 7650 0009 in section 9 (for more details see PCB circuit diagrams in section 9).

MicroGas 7650 includes the following assemblies:

3.1 Main PCB

The Main PCB contains the main processor, the I/O and memory decoding circuitry and all ROM and RAM. A timer/counter provides the loudspeaker frequency, the floating dc/dc converter frequency and the clock frequency for UART's and the parallel interface. A UART performs the serial communication with the floating board and another UART plus RS423 level shifter enables the communication with other Linde Medical Sensors systems (system connector). A parallel interface enables to drive a parallel printer. A PIO provides the interface to the Display PCB and the touch panel. A second PIO controls the loudspeaker, the calibrator valve and provides via a 10 bit DAC plus two S&H circuits the analog outputs of PO_2 and PCO_2 on the system connector and provides also the open collector status signals on the systems connector. It reads the pressure transducer signals of the calibrator on a comparator and reads the calibrator status signals. A real time clock (RTC) provides data and time and the time base (NMI) for the processor. There are also the oscillator for the system clock and the reset circuits. A watch dog timer circuitry, a low 5V detector and a low battery detector are also included. The PCB contains also +12V and -12V regulators and provides the calibrator value voltage. With 3 jumpers the following pre-settings are possible:

- Normal/Service operation
- mmHg/kPa (units) display
- GLEM (France) alarming.

3.2 Power supply PCB

The PSU PCB contains the mains transformer, rectifiers, 5V switching regulator, battery charger, low voltage (battery) detector and the on/off circuitry.

3.3 Floating board

On the Floating PCB the required isolation of the patient circuit is realised. The non-isolated (grounded) and the isolated (floating) parts are separated by a 11mm wide creepage barrier. The power of the isolated part is supplied by a pulse width controlled dc/dc converter via an isolation transformer and an optocoupler as feedback to control the pulse width. It provides regulated 5V and unregulated -5V. The communication between the two parts is performed by two optocouplers for serial data transmission and receiving. The non-isolated side of the board contains only the circuitry for driving the optocoupler and the dc/dc converter. The isolated side of the board is controlled by a microcontroller (processor) which performs the following tasks:

1. Receiving and transmitting serial data via the two optocouplers
2. Switching of the analogue MUX
3. Handling the A-D converter
4. Sensor type detection
5. Temperature setting via D-A converter
6. Heating on/off
7. Setting the negative supply for the sensor (-2V/-4V), (only Floating Board 7650 0813)
8. reading/writing from/to the sensor memory
9. Calculation of the PO_2 and PCO_2 values and of the sensor temperature
10. Controlling of the sensor calibration
11. Controlling of the sensor temperature

Tasks 1, 5, 7 and 10 are performed upon a specific request from the main processor (Main PCB). The other tasks are performed autonomous by the floating micro controller.

The sensor heating is regulated by a analog PI-controller with Thermistor 1 as the actual temperature and the DAC output as the set temperature.

The following adjustable reference voltages are provided:

+ 1.024 V	ADC Ref
- 2.000 V	Thermistor Ref and neg. supply of sensor
+ 2.500 V	DAC Ref
+ 1.200 V	Test Ref

3.4 Display PCB

The Display PCB contains the numeric LED controller and the LED digit driver circuitry, which control the six 7-segment LED's and the alarm off LED bar. It contains also the alpha numeric, LED backlighted LCD module, the LCD viewing angle adjustment circuitry and the backlight control (on/off) circuitry. Control and data signals are provided by the Main PCB.

3.5 Touchpanel

The touchpanel contains the six tactile keys (snap dome), the green "monitor on" LED and the yellow "mains" LED, the overlay and 3 window filters.

3.6 Calibrator assy

The electronic part of the calibrator assy consist of a bi-stable pulse valve consisting of two coils (open/close), a pressure transducer to check the gasflow, the pressure switch to check the gas bottle pressure and the calibration chamber switch to detect the presence of a sensor.

4 Installation

WARNING!

The following installation and acceptance procedure should be performed by a qualified technician.

CAUTION!

Do not connect the MicroGas to the ac mains power supply yet. Do not touch the line voltage setting when the MicroGas is plugged into the ac mains power supply. The ac mains fuses must have the correct current rating. When several equipments are interconnected, the total earth leakage current may constitute a hazard. If any power or earthing arrangement is suspect, the MicroGas must be powered from its internal battery.

4.1 Installation Checks

On receipt of a new MicroGas, check the following points for damage:

- Transport packaging
- Case
- Front and rear panels
- Connector sockets

Check that the MicroGas is accompanied by the following accessories, and check that they are not damaged:

- Operating manual
- Power cable assembly.
- Spare fuses: AC mains and DC

Check on the rear panel AC mains voltage plate, that the MicroGas has been set correctly for the AC mains supply from which it will be powered. If it is necessary to change the AC mains voltage setting, refer to section 4.3.

Check that the MicroGas is fitted with fuses of the correct current rating and type.

- 100 Vrms to 120 Vrms: 160mA (T)
- 200 Vrms to 240 Vrms: 80mA (T)

The fuse holder for these fuses is located just above the mains inlet plug on the rear panel. To open the fuse holder see section 4.3.1.

Connect the MicroGas equipotential earth terminal to a potential equalization conductor, if it is a mandatory requirement, or if a potential equalization conductor is available.

Plug the mains power cable into the rear panel AC mains power inlet and into a suitable mains power outlet, which must provide a protective earth (ground).

Perform the routine maintenance as described in section 5.2.

4.2 Location

The monitor should be located close enough to the patient so that the sensor cable will not be unduly stretched by movements that the patient might make. The alarms produced by MicroGas 7650 should be clearly audible from the operator's position. Lighting on and around the monitor should be such that the displays and indicator lamps are clearly legible and visible.

WARNING!

Never operate this equipment in the presence of flammable anaesthetics. Do not operate this equipment (sensor excluded) in an environment which has abnormal oxygen concentration. Do not expose the MicroGas to high humidity or heat. Keep plugs and connectors meticulously clean and dry. Do not allow any liquid to enter this equipment.

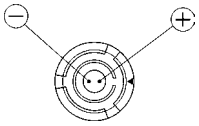
4.3 Changing the Mains Voltage Setting

The voltage selector is part of the mains inlet combi on the rear panel. The user has access to it from the outside.

1. Disconnect the mains cord and pull out the fuse drawer by using a tool like a small screw driver.
2. Pull out the marked voltage selector, turn it so that the new voltage range will be visible from the outside and then insert it again.
3. Insert the fuse drawer with the new fuses and check that the chosen voltage range is visible.

4.4 External DC Supply

If the unit is to be powered by an external battery (e.g. car battery) then assemble a two wire cable 16/02 Twin PVC with "Redel" plug type PAG-M02 GLAC 65G.

Polarity: 

(view: socket MicroGas rear panel)

Mark the wires of the free end of the cable with + and - and connect them correctly to the + and - pole of the battery.

4.5 Changing the Setting of the Measuring Unit from mmHg to kPa

1. Switch off the unit and disconnect from mains.
2. Follow section 6 steps 6.2 to 6.3 to get access to the Main PCB.
3. Set jumper JP1 on Main PCB to pins 1-2
4. Reassemble in reverse order.
5. Clean the area below the LED windows with soft cloth and alcohol.
6. Overpaint the mmHg indications with black permanent pen
7. Stick the kPa labels below the windows so that they cover the overpainted mmHg indication (take care that they are parallel and inline to the windows
8. Check correct link placement and operation by:
   - Connecting a sensor or a simulator
   - Switch unit on
   - Check decimal point is displayed XX.X on the PO_2 and PCO_2 displays
9. Carry out routine safety and performance check

5 Maintenance and Fault Finding

5.1 Introduction

The recommended routine maintenance is split into two levels:

- Section 5.2 describes the routine maintenance procedure which should be carried out monthly on-site by the operator.
- Section 5.3 describes the routine safety and performance check which should be performed at regular intervals e.g. every two years or in accordance with local and governmental regulations.

In addition to the two routine maintenance procedures, section 5.4 describes the adjustment and performance check procedure which shall be performed after a repair.

WARNING!

Electrical safety testing must be performed at least on the following occasions:

- **Immediately following a check as described in section 5.3.**
- **Whenever the equipment has been repaired or adjusted.**
- **If the equipment has been damaged, or damage is suspected.**
- **If the equipment fails any of the tests, the fault must be found and rectified. The equipment must then be fully re-tested and its electrical safety found to be satisfactory, before it can be brought back into use.**

Section 5.5 gives the procedure to be followed to check that the equipment is electrically safe.

Section 5.6 information on decontamination, which should be undertaken before any inspection, service or repair.

WARNING!

If there is any risk that the equipment is contaminated, you must follow the decontamination procedure given in section 5.6

Section 5.7 describes the replacement of the internal battery.

Section 5.8 describes monitor fault codes.

WARNING!

This equipment's cover must not be removed by unqualified persons. Disconnect the equipment from the mains power supply before removing the cover. Take extreme care if the mains power supply is re-connected when the equipment's cover has been removed.

5.2 Routine Maintenance

Action

1. Check Monitor
2. Check Sensor
3. Check Consumables

The routine maintenance should be performed monthly according to the following procedure:

5.2.1 Check Monitor

- Switch monitor off and disconnect it from AC power.
- Clean housing, front and rear panel with a soft cloth lightly moistened with warm soapy water. Use only mild soap or detergents. Allow to dry completely before use.
- Inspect power cord assembly for any signs of mechanical damage to cable or connector. If damaged, replace with a genuine Linde Medical Sensors replacement part. Do not attempt to repair.
- Connect Monitor to AC power.
- Switch Monitor off and on again.
- Verify that during the following self-check, all display segments and control lamps are illuminated, that all dots of the middle LCD are visible and that a tone sounds.
- Check parameter settings and readjust if required.

5.2.2 Check Sensor

- Check sensor and cable assembly for any signs of mechanical damage. In case of a damage, replace sensor. Do not attempt to repair.
- Clean the prepared sensor and the cable with a soft cloth moistened with alcohol (carefully avoid damaging the delicate sensor surface). Allow to dry completely before use.
- Remembrane sensor if required.

5.2.3 Check Consumables

- Check expiration date of all consumables. Replace if necessary.

5.3 Routine Safety and Performance Check

At normal use of the monitor there is no internal adjustment or new calibration of the monitor required. It is recommended to perform a safety and performance check at regular intervals e.g. every two years when the internal battery must be replaced (see section 5.7) or in accordance with local and governmental regulations. The routine safety and performance check must be done by a trained and authorized service technician only.

Action

1. Inspection
2. Performance test
3. Safety test

Equipment required

- Electrical Safety Tester
- MicroGas 7650 Service Manual
- Cal-Gas bottle, Part number 064 0210

5.3.1 Inspection

Check the general condition of the case, external controls, overlay and mains lead

Inspect the sensor cable and the sensor head

Remove the four screws from the base (refer to section 6), remove the case and perform an internal inspection, check for possible fluid ingress and the security of the PCB's, plugs and sockets.

Re-assemble unit.

5.3.2 Performance test

Connect the sensor at the rear and insert the sensor head into the "autocal" calibration chamber.

1. Switch the unit on at the rear and ensure that the following are displayed:

   7650 SYSTEM TEST
   followed by: 7650 REV. 12.00
   followed by: FLOAT REV. 4.00
   (numbers are example)

   The unit should then enter the CALIBRATING mode.

2. Within 10 minutes ensure that the unit displays:

   READY TO USE
   (with actual date and time)

   If the calibration takes up to 20 minutes then the sensor needs to be stabilized.

   If REMEMBRANE SENSOR is displayed, remembrane the sensor and perform a new calibration.

   If REMEMBRANE SENSOR occurs again, let the sensor be placed in the calibration chamber for stabilization for up to 4 hours or exchange the sensor.

3. Remove the sensor from the "autocal" calibration chamber and leave the sensor head in air.

   Within 2 minutes the unit will display a PCO_2 reading of less than 5 mmHg (0.7 kPa) and a PO_2 reading which amounts at least to the calibration value mulitplied by the factor 1.5.
   (e.g. 90 mmHg x 1.5 = 135 mmHg or 12.0 kPa x 1.5 = 18.0 kPa)

4. Apply the sensor to the inside of your left upper arm by following the instructions, given in the operating manual in section 3.6. Set the site timer to 30 minutes. Press the START key so that the site timer runs down while you perform the following remaining steps in this section.

5. Allow approx. 10 minutes for the sensor to stabilize. Do not move to avoid erratic readings. Verify that the readings are within the following limits:
   - PCO_2 = 34 mmHg to 45 mmHg (4.5 kPa to 6.0 kPa)
   - PO_2 = 60 mmHg to 90 mmHg (8.0 kPa to 12.0 kPa)

6. Ensure that the "Mains connected / internal battery charging" and the "Monitor On" indicator lamps are on.

7. Test all front panel keys for operation.

8. Return to normal monitoring, enter in each alarm menu (of PO_2 and PCO_2) and change each alarm limit, one after the other, in order to provoke alarm conditions. Verify that each alarm is correctly indicated.

5.3.3 Safety test

Earth leakage, patient leakage, insulation and earth bonding tests should be carried out and the results recorded (Details see section 5.5).

5.4 Adjustement and Performance Check

This procedure shall be performed following to a repair of the monitor (exchange or repair of a sub-assembly). Depending on the type of the repair it may be sufficient to perform only parts of this procedure. Following to this procedure the Electrical Safety Check (see section 5.5) must always be performed. The Adjustment and Performance Check must be done by a trained and authorized service technician only.

Action

1. Check inscriptions and labels
2. Inspect all plugs and cables
3. Check fuses
4. Check start up
5. Check retention of parameter and alarm settings
6. Check alarms
7. Check battery
8. Check Main PCB voltages
9. Check floating board supply and voltage references
10. Check heating and sensor fault
11. Check PO_2/PCO_2 measurement
12. Check analog outputs
13. Check pressure transducer and pressure switch
14. Check access to sensor memory
15. Check battery charger
16. Check electrical safety

Equipment required

- DVM 5 digit
- Blood Gas Sensor Simulator II
- Dummy Sensor head
- Combi•M Sensor
- Cal-Gas bottle, part number 064 0210

Action details:

5.4.1 Check inscriptions and labels

Check that inscriptions and labels are complete and legible.

5.4.2 Inspect all plugs and cables

Inspect all cables for signs of damage or loose connections. Replace or re-connect as necessary.

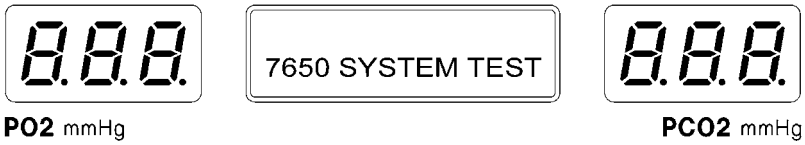
5.4.3 Check fuses

Check that the fuses are the correct type and rating.

5.4.4 Check start-up

- Connect MicroGas to the AC mains supply. The front panel yellow power lamp (⏽) shall light.
- Switch the monitor on (on/off switch on rear panel). The front panel green ON lamp (⊙) shall light.
- Check for the following displays

During the first approx. 4 seconds:



Alarm LED (🔔) lights

During the following approx. 4 seconds:

The Alarm LED D1 and all six seven segment LED's are switched off.

The central LC-display shows the following:

	7650 REV. 12.00 (Revisionnumber = example)
followed by:	FLOAT REV. 4.00
then the display changes to:	CONNECT SENSOR

The LED-Backlight is flashing; on-off / sec

The Fault tone sounds

During all these display sequences, give your attention to the following:

- all displayed messages are displayed correctly
- all characters are correct, no missing dot
- uniform intensity of all displayed dots
- uniform brightness of all green segments of the LED's
- even, yellow illumination over the whole display area of the central display.

5.4.5 Check retention of parameter and alarm settings

Switch monitor off (rear panel). Wait for approx 10 seconds, switch monitor on again. Select with P-key all parameters and alarms and check that the values have been retained (not overwritten by default values) and that the actual date and time is displayed.

5.4.6 Check alarms

Check that PO_2 and PCO_2 high and low alarms can be activated. Connect a COMBI•M sensor (rear panel) and perform a calibration, refer to operating manual section 3.2. Remove the sensor from the calibration chamber and apply it to a patient or to yourself as described in section 3.6 of the operating manual. Start a measurement as described in section 3.7 of the operating manual. Wait for at least 5 minutes then alter each alarm limit so that the current value causes an alarm to be activated. Disable alarms before adjusting limits. Enable alarms and press the alarm off/reset key as soon as the audible alarm sounds. Change the limit so that the current value does not cause an alarm. Repeat the process until maximum and minimum alarm limits have been tested for both parameters.

5.4.7 Check battery

1. Disconnect mains cord. Ensure that the monitor operates from its internal battery.

2. If "Charge Battery" appears, connect the monitor to AC mains for at least 12 hours. Operate the monitor again on battery and check that "Charge Battery" is not displayed. If it is, the battery may need replacing.

5.4.8 Main PCB voltages

1. Connect the Mains Supply to the rear panel Mains Socket.
   Check that the yellow LED (ⓘ) on the front panel lights.
   The following measurements are to be performed on the Mainboard

2. Raw DC-Supply
   Connect DVM⊖ to TP0
   DVM⊕ to TP 5: 22,0 V to 30,0 V
   DVM⊕ to TP 6: 21,5 V to 29,5 V

3. Check RAM and RTC supply:
   DVM⊕ to TP2: 2,4 V to 2,6 V

4. Supply voltages:
   • switch monitor on (rear panel on-off switch)
   • check the green LED (⊙) is lit on the front panel
   • measure the following voltages:

TP 5:	20,0 V	to	26,8 V
TP 6:	19,2 V	to	26,0 V
TP 7:	4,9 V	to	5,1 V
TP 9:	19,3 V	to	26,1 V
TP10:	11,8 V	to	12,4 V
TP11:	-10,0 V	to	-11,4 V

5.4.9 Floating board supply and reference voltages

1. Set Bloodgas Sensor simulator to:

Rotary	Switch "SENSOR"	=	Combi
Rotary	Switch "PCO_2"	=	2 (35mmHg)
Rotary	Switch "PO_2"	=	2
Rotary	Switch "TEMP.°C	=	44
	Switch "ΔTh1°C	=	0
	Switch "ΔTh2 Ω	=	OFF
	Switch "Cathode"	=	shorted

   Connect Simulator to Sensor input on the rear panel.
   The display changes to the following:
   - Numeric display shows PO_2 and PCO_2 values (depending on previous calibration)
   - The central display changes to either:
     a) S. REMEMBRANED ? or: b) CALIBRATE SENSOR
     NO =▼ YES =▲

2. In case of text a) press [△] key.
   Central display shows: CALIBRATE SENSOR

3. Else continue with next step.
   Set Monitor to:
   - BAROMETRIC PR. = 750 mmHg
     (9 x [P] key, followed by [▽] or [△] key)
   - PCO2 TEMP. CORR. FACTOR = 1.50
     (select Parameter Level 2 via 11 x [P] key then during 2 sec. [△] key, then another 6 x [P] key followed by [▽] or [△] key)
   - PCO2 METABOLIC. CONSTANT = 0 mmHg (0.0kPa)
     (Select Parameter level 2, then 7 x [P] key followed by [▽] or [△] key)

4. Screw the Calibration Gas Bottle into the Calibrator part of the monitor (Rear panel aperture)

5. Put a dummy sensor head into the calibration chamber; the central display changes to:

   CALIBRATING
   90 mmHg 35 (12.0 kPa 4.7)

   and the gas value opens audible after maximum 60 seconds. While the unit is calibrating, proceed with the test

6. Supply voltages:

   DVM⊖ to TP9
   +5V on TP7 = 4,85V to 5,15V
   -5V on TP8 = -4,75V to -5,50V

7. Reference voltages:

   a) -2V ref on TP12 = - 2,000V ±0,4 mV, if necessary readjust with potentiometer RV1
   b) 1,024V ref on TP10 = +1,024V ±0,1 mV, if necessary readjust with potentiometer RV2
   c) +2,5V ref on TP11 = +2,5V ±6 mV
   d) Control reference on TP 17 = +1,205 V to + 1,260 V

5.4.10 Heating circuit and Sensor Fault

1. Heating adjustment:

   DVM⊕ to TP 13, reading must be 0V ±20 mV, if necessary readjust with RV3.
   Wait until the calibration has finished (max 90 sec since 5.4.2.5 if no readjustments have been performed) and the central display shows:

   READY TO USE
   JUN. 01/99 14:30

   Remove the dummy sensor head from the calibration chamber; the central display changes to:

   100 44.0 50
   50 4:00 25

   alternating with:

   PRESS START
   MONITORING

   Press ⏀ key, the central display changes to monitoring mode:

   100 44.0 50
   50 4:00 25 (" : " is flashing)

2. Select 37,0°C on the sensor simulator
   The displayed temperature flashes.

3. Select successively all temperature values between 37°C and 45°C on the sensor simulator and compare the set temperature with the temperature indicated on the display.
   Deviations shall not exceed 0,1°C.
   At 44,0°C, flashing shall cease and recover at 44,5°C.

4. Leave the temperature setting on the simulator on 45,0°C. After 4 seconds, the message:
   SENSOR FAULT
   accurse together with the fault tone.

5. Leave temperature setting at 45°C. After again 4 seconds the message shall change to:
   MONITOR FAULT 7

6. Reset alarm by turning the monitor off then on again. Set simulator to 44.0°C.
   In case of display showing:
   S.REMEMBRANED ?
   press ▲ key.
   Display changes to:
   CALIBRATE SENSOR
   Then press ⏻ key. Monitoring display alternate with:
   CALIBRATE SENSOR

7. Connect DVM to sockets "+" and "GND" on sensor simulator.

8. Set temperature to 43,5°C on simulator.
   The DVM reading shall increase and settle at a value between 6V and 9,5V.

9. Set temperature to 44,5°C on simulator.
   DVM reading shall decrease and settle at a value less than 0,8V.

10. Set temperature to 44,0°C on simulator. Note displayed temperature. Set " ΔTh1°C" on simulator to "-0,1°C". Displayed temperature shall decrease by 0,1°C. DVM reading shall show a step change followed by an increase at a rate off approx. 150 mV/sec ±50%.

11. Set "ΔTh1°C" on simulator to "+0,1°C". Displayed temperature shall increase by 0,2°C. DVM reading shall show a step change followed by a decrease at a rate of approx. 150 mV/sec ±50%.

12. Set "ΔTh1°C" to 0 on simulator and set "ΔTh2Ω" to ON on simulator.
    Turn ΔT2 - potentiometer to positive values until the temperature indication on the monitor starts flashing. This shall occur at 36 Ω < ΔTh2 < 72 Ω. The DVM reading shall be independent of the ΔTh2 value.

13. Repeat step 12 with negative values of ΔTh2. Set "ΔTH2" to OFF on simulator. Disconnect multimeter.

Note: Take care that the temperature display does not flash more than 30 seconds, else SENSOR FAULT will be displayed.

5.4.11 Check of PO_2/PCO_2 Measurement

1. Check that the sensor simulator is set according 5.4.9, step 1.

2. If the calibration was successful in 5.4.10, step 1. then the numeric display shall indicate now:
   PO_2 = 90 mmHg ±1 (12,0 kPa ±0,1), PCO_2 = 35 mmHg ±1 (4,7 kPa ±0,1)

3. Select position 1 to 6 on "PO_2" rotary switch of simulator.
   Numeric display shall indicate the following values:

Simulator	Numeric display
1	43 - 47 mmHg (5,7 - 6,3 kPa)
2	89 - 91 mmHg (11,8 - 12,2 kPa)
3	174 - 186 mmHg (23,2 - 24,8 kPa)
4	440 - 460 mmHg (58,6 - 61,4 kPa)
5	700 - 740 mmHg (93,3 - 98,7 kPa)
6	740 - 790 mmHg (don't care)

4. Select all 4 positions on "PCO_2" rotary switch of the simulator.

   The values indicated on the monitor shall be:

Simulator	Monitor
1	14 - 16 mmHg (1,8 - 2,2 kPa)
2	34 - 36 mmHg (4,5 - 4,8 kPa)
3	79 - 83 mmHg (10,5 - 11,1 kPa)
4	179 - 193 mmHg (EEE)

5.4.12 Analog output (Systems Connector)

1. Reference voltage adjustment: Connect DVM⊕ to TP14 on Main PCB, 0 V = TP0.

   Adjust voltage with potentiometer RV 1 to: + 2,482 V ±1mV

2. PO_2 output: Connect DVM⊕ to TP 22 on Main PCB.

   Repeat PO_2 measurement as described in section 5.4.11, step 3.
   max. output = 6,0V, therefore only step 1, 2 and 3 of the simulator are possible
   The DVM reading shall be: Displayed PO_2 value multiplied by 20mV ±2%

3. PCO_2 output: Connect DVM⊕ to TP23 on Main PCB.

   Repeat PCO_2 measurement as described in section 5.4.11, step 4.
   The DVM reading shall be:
   Displayed PCO_2 value multiplied by 20 mV ±2%

5.4.13 Pressure transducer and pressure switch

1. Put a dummy sensor head into the calibration chamber.

   The central display changes to:

   CALIBRATING
   90 mmHg 35 (12.0 kPa 4.7)

   and the gas valve opens audible after maximum 60 seconds.

2. Screw out the gas bottle

   The central display must change to:

   NO GAS FLOW (flashing)
   RENEW GAS BOTTLE

   and the fault tone sounds

3. Screw in the gas bottle again. The central display changes back to the calibrating text and the faulttone is muted.

5.4.14 Access to Sensor Memory

Select Parameter Level 2 on Monitor; 11 x [P] key than 2 seconds [△] key, then again 13 x [P] key

The central display shall show:

LAST SLOPE ADJ.
JUNE 26/97

The date displayed shall be the date of the last Slope Adjustment of the Sensor Simulator.

5.4.15 Battery charger:

1. Disconnect the dc-supply.
   Set DVM to measure current and connect it to plug JP3 of the PSU PCB.
2. Connect unit to mains and switch it on.
3. Measure charger current.
   DVM reading must be between 120 mA and 200 mA

5.4.16 Safety checks

See section 5.5

5.5 Electrical Safety Checks

WARNING!

Electrical safety can be assured by frequent safety testing. Safety testing, i.e. all of the tests in this sub-section, must be performed at least on the following occasions.

- **Immediately following the routine safety and performance check.**
- **Whenever the equipment has been repaired or adjusted.**
- **If the equipment has been damaged, or damage is suspected.**

If the equipment fails any of the tests, the fault must be found and rectified. The equipment must then be re-tested and its electrical safety found to be satisfactory, before it can be brought back into use.

Earth leakage current, patient leakage current, insulation and earth bonding tests must be performed and the results recorded.

Equipment required: Electrical Safety Tester

Measurement and test values:

Earth leakage current	normal/reverse < 500 uA
Patient leakage current	< 20 µA at 200 - 240 Vrms < 10 uA at 100 - 120 Vrms
Insulation	> 50 MΩ
Earth bonding	< 0.2 Ω

5.6 Decontamination

5.6.1 Decontamination requirements

Due to the nature and seriousness of diseases such as acquired immunodeficiency syndrome and Hepatitis B, it is important that where equipment and accessories can come into contact with human or animal tissues or fluids (particularly blood), they should always be regarded as contaminated and potentially hazardous.

Contaminated equipment and accessories must be decontaminated in accordance with the hospital decontamination and disinfection procedures appropriate for the device, or by the following procedure.

Decontamination must be carried out by properly trained staff.

If you are in any doubt regarding contamination or decontamination, consult your local infection control officer.

5.6.2 Risks

All human or animal tissues or fluids in the hospital and laboratory environment are capable of transmitting infection. Therefore, special precautions must be taken in hospitals and laboratories that deal with patients who have highly infectious disease.

Disease can enter by the following routes:

- Through broken skin
  - needle or other sharp object
  - contamination of cuts, abrasions or burns
- Ingestion (placing a contaminated object in or near the mouth, e.g. pen, finger)
- Direct contact with mucous membranes (e.g. eyes)
- Inhalation of contaminated dust or aerosols

Experience has proved that when proper precautions are taken, as outlined below, the risk of infection is very small and certainly of a lower order of magnitude that other risks that are taken routinely in daily life.

5.6.3 Precautions

The following precautions must be taken to avoid risk of infection. Different levels of compliance may be observed in different areas, but only constant adherence to all precautions is sufficient to ensure personal health and safety.

Containment

Although the hospital or laboratory is responsible for ensuring that any spillage of body fluids is properly cleaned and that equipment is decontaminated, it cannot completely assure that all traces of contaminant have been removed, particularly from internal parts of equipment which are accessible only during servicing.

Sharps

Take particular care to avoid puncture wounds from needles or cuts and abrasions from sharp edges.

Protective clothing

A laboratory coat, surgeons' disposable gloves and a plastic apron must be worn for all service work in clinical areas. Safety glasses and a paper face mask must also be worn if there is any risk of dust or aerosol formation. Renew gloves frequently and wash hands thoroughly before putting on a new pair.

Renew gloves immediately if they become punctured, cut or torn.

The correct method of removing disposable protective clothing is as important as wearing it in the first place. Carefully fold aprons inwards and remove gloves by pulling them from the cuff to turn them inside-out. Take care not to touch the contaminated outside surface.

Immediately after use, place all items of disposable protective clothing in the appropriate receptacle for biological waste, as advised by the laboratory. Never re-use disposable protective equipment.

Personal hygiene

Scrupulous personal hygiene is probably the most important precaution in eliminating the risk of infection. Always wash hands and face with soap and water and scrub nails after completing each service, or when leaving the clinical laboratory to take a break.

Avoid hand contact with the mouth, eyes, ears and nose.

Eating and drinking

Never eat, drink or smoke in any contaminated area.

Cuts and abrasions

Infection can enter the body through any cut, abrasion, chapped skin, open sore or spot, or skin affected by eczema. Ensure that any cut, abrasion or sore is covered with a waterproof dressing. Use hand cream to prevent chapping and do not touch any other infected area of skin until your hands have been thoroughly washed.

Accidents

Action in the event of accidental contamination should be as follows:

- Cuts: Remove gloves or any other items clothing which could introduce contamination, encourage the wound to bleed freely and wash it thoroughly under running water. Seek further advice and treatment from any occupational health or casualty department, if such services are available. Otherwise, minor cuts should be dried using a sterile gauze,and a waterproof dressing should then be applied.
- Eye contact: Irrigate thoroughly with water and obtain medical attention if necessary.
- Skin contact: Wash gently under running water.

Note: Any cut or other injury sustained while servicing equipment must be reported to your Supervisor.

5.6.4 DO's and DON'Ts

- DO wear a laboratory coat, apron and gloves.
- DO disinfect contaminated surfaces.
- DO disinfect tools after use.
- DO wash thoroughly before leaving the contaminated area.
- DO dispose of gloves and aprons immediately after use, or if damaged.
- DO treat any cut or abrasion immediately.
- DO keep cuts and abrasions covered with a waterproof dressing.
- DO encourage any cut to bleed and then wash it under running water.

- DON'T put hands near mouth, eyes, ears or nose.
- DON'T eat, drink or smoke in any contaminated area.
- DON'T blow surfaces to remove dust; use a vacuum cleaner

5.6.5 Decontamination procedures

CAUTION!

DO NOT STERILIZE THE EQUIPMENT AND ACCESSORIES BY IRRADIATION, STEAM OR ETHYLENE OXIDE. ELECTRONIC EQUIPMENT AND ACCESSORIES NOT SUITABLE FOR AUTOCLAVING. USE A CHEMICAL DESINFECTION SOLUTION AS DESCRIBED BELOW.

Please refer to section 5.2 of this manual for the recommended cleaning procedure for each device.

Chemical disinfection

Where an equipment has been used but is not visibly contaminated, first wipe its surface with cotton wool swabs soaked in isopropyl alcohol (70%), and then dry the surface with a disposable cloth.

Where surfaces of equipment or accessories are visible contaminated, wipe the surface with cotton wool swabs soaked in a surface disinfection solution containing e.g. quaternary ammonium derivates, to remove all visible traces of soiling. Then apply the disinfection solution to the surfaces, keeping them wet according to the recommandations of the disinfection solution manufacturer. Rinse the surfaces with water and then dry them using disposable cloths.

Dispose of swabs in the receptacle for biological waste, immediately after use.

Take care that liquids do not enter the equipment or connectors.

Use of other disinfectants

Other chemical disinfectant solutions are not suitable for use on delicate medical equipment and accessories as they can cause permanent damage and corrosion. In particular, hypochlorites and chlorinated ketone, ether or ester-based solvents must not be used.

Dust removal

Remove dust by using a vacuum cleaner, never blow surfaces to remove dust. Always wear gloves, face mask and eye protection when replacing vacuum cleaner bags. Place the full bag inside a polythene bag, seal with tape and place in the appropriate receptacle for biological waste.

Equipment requiring service

Where equipment or accessories are to be returned to the supplier or factory for service/repair, the clinical user must ensure that the device has been properly decontaminated. A certificate of decontamination must be completed by the person responsible for the device and this certificate must accompany the device on its return for service or repair.

Where equipment is to be serviced on site, a certificate of decontamination will also be required by the service engineer.

Linde Medical Sensors AG
Austrasse 25
4051 Basel
Switzerland

Tel.: 41-61 278 81 11
Fax: 41-61 278 81 81

CLEARANCE CERTIFICATE

for the Inspection, Servicing, Repair or Return of Medical and Laboratory Equipment.

TO: (Manufacturer/Supplier) .....

.....

.....

Manufacturers Service Ref/
Returns Authorisation Ref: .....

Customers Ref/Order No: .....

Make & description of equipment:

.....

.....

Model/Serial/Batch No. .....

Other distinguishing Marks .....

A. Has this equipment been exposed internally or externally to any of the following. Please answer all questions by deleting Yes/No as applicable and by providing details in Section B below.

1. **Blood, body fluids, pathological specimens** Yes/No
2. **Other biohazard**
   Provide details below Yes/No
3. **Biodegradable material that could become a hazard**
   Provide details below Yes/No
4. **Chemicals or substances hazardous to health**
   Provide details below Yes/No
5. **Radioactive substances**
   State below name(s) and quantities of isotopes and chesks made for residual activity Yes/No
6. **Other hazards**
   Provide details below Yes/No

B. Please provide details of any hazards present as indicated above, include details of names and quantities of agents as appropriate.

.....
.....

C. Your method of decontamination (please describe).

.....
.....

D. Are there likely to be areas of residual contamination (please specify).

.....
.....

I declare that the above information is true and complete to the best of my knowledge and belief.

Authorised Signature: ..... Date: .....

Name (printed): ..... Position: .....

Customer's Name: ..... Dept.: .....

Address: ..... Tel.: .....

5.7 Replacement of Internal Battery

The MicroGas monitor internal battery is recharged automatically while the monitor is connected to mains. When the monitor is not in use and not connected to mains for more than 6 months, the battery charge must be refreshed.

For a full charge connect the MicroGas monitor to mains power for 18 hours.

To keep the charging state of the internal battery at maximum, leave the monitor connected to AC power. In case the system should not be connected to AC power for an extended period of time (several months) it is recommended to disconnect the battery.

It is recommended to replace the internal battery every two years (see also section 5.3, Routine Safety and Performance Check).

For disconnection, removal or replacement of the internal battery refer to section 6.6.

5.8 Fault Finding

5.8.1 Sensor Fault

Indication: display shows the flashing message "SENSOR FAULT" and the fault tone sounds.

Whenever a sensor fault is detected the sensor heating is automatically switched off.

The sensor fault is triggered by the following conditions:

1. The contents of the sensor memory has been lost, or the access to the sensor memory is not possible.

   Check sensor connector, flexi PCB, input buffer IC U9 and GAL IC U4, all located on the floating board.

   If the sensor memory is in doubt then the complete sensor must be replaced.

2. Temperature fault - one of the following condition is fulfilled:
   - actual temp. > set temp. + 1°C for 4 sec
   - actual temp. < set temp. - 1°C for t_{max} (maximum time)
   - t_{max} is normally 30 sec but 5 min during warming up of the sensor.
   - (actual temp.- set temp.) > 0.3°C for t_{max}
   - difference between thermistors > 0.6°C for 4 sec.
   - difference between thermistors > 0.3°C for t_{max}

   Check the following on the floating board:

   Sensor connector, Flexi PCB, multiplexer IC U8, DAC IC U10 and IC U11, heating regulator IC's U12 and U13 and associated components. Check the concerned tracks on breaks and short circuits.

5.8.2 Monitor Fault Codes

The monitor has detected an irregularity of one of its functions.

Indication: display shows the flashing message "MONITOR FAULT XX" (XX = code number) and the fault tone sounds.

Whenever a Monitor fault is detected the supply voltage of the floating board is switched off automatically and any measurement is stopped.

Code	Cause	Remedy
3	Communication error between Floating board and Main board. No reply from Floating board.	Check floating supply voltage, opto-couplers OC2 and OC3, microcontroller IC U3 on float board, UART IC U29 on main board and ribbon cable 7650 0062.
5	Communication error Floating to Main pcb. Wrong data replied or parity error.	Check optocouplers OC2 and OC3, micro-controller IC U3 on float. board, UART IC U29 on main board.
6	Sensor heating is switched off but temperature is still higher than the selected temperature since 4 minutes.	Check heating circuit and analog multiplexer. Check transistors Q9 and Q10 on float. board.
7	Sensor heating is switched off but temperature is higher than 44°C since 4 seconds	Refer to fault 6
8	RAM error on main board.	Check RAM circuit: DBUS, control bus, voltage supply. If necessary exchange RAM'S.
9	RAM error on floating board.	Check floating board micro-processor circuit. If necessary exchange it.
10	Microprocessor on Floating board does only communicate with the Main-board but is no more performing the measurement task.	Check on Floating board eProm, Micro-processor, Multiplexer. If necessary exchange them.
12	AD-converter error on floating board.	Check reference voltages: Test ref., +1.024V ref., -2V ref., +2.5V ref. (D10, D6, IC U14, Q7 and associated components) and multiplexer.
20	Watch Dog Error: The main board processor is interrupted by a non-maskable interrupt (NMI) because the watch dog timer has switched off (not retriggered) within 1 second.	Processor failure: Check D-bus, A-bus, Control bus, EPROM, RAM, GAL IC U17 and IC U3. Check concerned sockets and tracks an breaks and short circuits.
21	Watch Dog Test error detected during power up.	Check IC U3, GAL IC U17, Latch IC U26. Check tracks on breaks and short circuits
30	Check sum of the instruction memory of the main pcb is incorrect	Check connections to EPROM IC U5, A-Bus, D-Bus and control-bus. If necessary exchange EPROM

5.8.3 Gas System Faults (Calibrator assy)

Warning message	Cause	Remedy
GAS FLOW DISTURBED F1/F2	During calibration the monitor has detected an irregularity of the pressure control system	Exchange complete calibrator assy
NO GAS FLOW RENEW GAS BOTTLE occurs too early (when more than 4 dot of the bottle filling bar graph are displayed)	Calibrator assy disadjusted (too high gas flow or thres-hold of pressure switch too low or defective comparator)	Check comparator-circuit on main board IC U15 and U25 if necessary exchange cali-brator assy (do not adjust)

6 Removal and Refitting

WARNING!

This equipment's cover must not be removed by unqualified persons.

Disconnect the equipment from the mains power supply before removing the cover. Take extreme care if the mains power supply is re-connected when the equipment's cover has been removed.

6.1 Mains Fuses and Voltage Selector

6.1.1 Operating the Fuse Holder

1. Insert the tip of a small screwdriver under the tab of the fusedrawer (the mains cable assembly must be umplugged).
2. Twist the screwdriver to lever up the fusedrawer and pull the fuse drawer out of its compartment.
3. The fuses are now easily accessible

6.1.2 Setting of the Mains Voltage Range

After the fusedrawer has been pulled out (6.1.1) also the voltage selector insert can be pulled out by means of a pincers. If the alternative mains voltage range must be set turn round the insert and push it back into its compartment. Check that the desired voltage range identification number is visible.

6.1.3 Refitting the Fuse Holder

1. Check that the fuses correspond to the desired mains voltage range.
2. Insert the fusedrawer into its compartment and push it flush with the surface of the AC mains inlet assembly.

6.2 Case

6.2.1 Removing the Case Assembly

1. Remove the four pan head screws which are located on each side underneath the base of the unit.
2. Pull forward the complete case assembly (Frontpanel, Touchpanel, Sensor spool and hood) until the inside of the unit is free.
3. Turn the case assembly onto its left side and place it to the left side of the unit.

6.2.2 Refitting the Case Assembly

Refitting is the reverse of removal

6.3 Main PCB

6.3.1 Access to Main PCB

1. Remove the two screws that secure the interface plate of the Main PCB to the rear panel of the chassis.
2. Remove the screw from the right-hand edge of the Main PCB (front view).
3. Hinge up the Main PCB. The component side of the Main PCB is then accessible.

6.3.2 Removal of the Main PCB

1. With the Main PCB hinged up, disconnect the ribbon cable assemblies from PL3, PL4, PL5 and PL6, and the loudspeaker cable assembly from PL7.
2. Close the Main PCB and remove the two screws that secure the hinge to the Main PCB.

6.3.3 Refitting the Main PCB

Refitting the Main PCB is the reverse of removal.

6.4 Floating PCB

6.4.1 Access to Floating PCB

1. With the Main PCB hinged up remove the two screws that secure the sensor input connector to the rear panel.
2. Remove the screw that secures the insulation sleeve assembly to the inside of the front wall of the chassis.
3. Hinge up the Floating PCB assembly. Remove the insulation sleeve by sliding it backwards.
4. Remove both screw on the inner can cover and remove the inner can cover. The component side of the Floating PCB is then accessible.

6.4.2 Removal of the Floating PCB

1. With the Floating PCB hinged up, disconnect the ribbon cable assembly from plug JP1.
2. Remove the two screws that secure the hinge to the Floating PCB.

6.4.3 Removal of the sensor input socket assembly

1. Disconnect the flexi PCB from socket JP3.
2. Remove the two screws that secure the sensor input socket assembly (solder side of the PCB).

6.4.4 Refitting the Floating PCB

Refitting is the reverse of removal.

6.5 Power Supply PCB

6.5.1 Access to Power Supply PCB

Hinge up the Main PCB (6.3.1) and hinge up the Floating PCB assembly (6.4.1), the component side of the Power Supply PCB is then accessible.

6.5.2 Removal of the Power Supply PCB

1. Disconnect the ribbon cable assembly from plug JP4, the on/off cable assembly from JP2, the dc-input cable assembly from JP1, the battery cable assembly from JP3 and the five single wires from J1, J2, J3, J4 and J5.
2. Remove the four screws that secure the PCB to the chassis bottom.

6.5.3 Refitting of the Power Supply PCB

Refitting is the reverse of removal.

6.6 Battery

6.6.1 Removal of the Battery

1. Hinge up the Main PCB (6.3.1) and hinge up the Floating PCB (6.4.1)
2. Disconnect the battery leads
3. Remove the three screws (two on the left side and one on the right side of the battery clampfront view) which secure the battery clamp.
4. Remove the battery clamp and lift the battery clear of the unit.

6.6.2 Fitting a Battery

Fitting a battery is the reverse of the removal. Take care when reconnecting the battery leads that the battery polarity is correct.

6.7 Display PCB

6.7.1 Access to the Display PCB

Remove the case assembly (6.2.1) then the component side of the PCB is accessible.

6.7.2 Removal of the Display PCB

1. Disconnect the touch panel ribbon cable assembly from socket JP1.
2. Remove the four screws that secure the PCB to the front wall of the chassis.
3. Pull forward the PCB slightly and disconnect the ribbon cable assembly from plug JP3 on the solder side of the PCB.

6.7.3 Refitting of the Display PCB

Refitting is the reverse of removal.

After the Display PCB is fitted make sure that the PCB can be pushed backwards against the four springs (one per stud).

6.8 Touch Panel

6.8.1 Removal of the Touch Panel

1. Remove the case assembly (6.2.1), then remove the ribbon cable assembly from socket on touch panel rear side.
2. Remove the six nuts on the inside of the front panel that secure the touch panel to the front panel.

6.8.2 Refitting of the Touch Panel

Refitting is the reverse of removal

6.9 Calibrator Assembly

6.9.1 Removal of Calibrator Assy.

1. Pull out the brief operating instructions card.
2. Remove the two pan head screws that secure the calibrator assy to the chassis bottom. The screws are accessible through holes in the user card guide.
3. Hinge up the Main PCB (6.3.1) and hinge up the Floating PCB (6.4.1).
4. Disconnect the collored ribbon cable assembly from PL5 on the Main PCB.
5. Remove the screw that secures the calibrator assy to the rear panel.
6. Lift the calibrator assy clear of the unit

6.9.2 Refitting of the Calibrator Assy.

Refitting is the reverse of removal.

Note: When refitting the calibrator assy make sure that the positioning pin fits well to the positioning hole which is located between the two fixing holes in the chassis bottom.

7 Parts List and Assembly Drawings

7.1 Introduction

The following parts lists provide the component and assembly part numbers that may be used to order spares and replacements.

7.2 Recommended Spare Parts

7.2.1 Recommended number of spare parts

LMS recommend that the following spares are held, according to the number of MicroGas 7650 to be serviced. Add column A and B for 6 to 20 7650's, columns A, B and C together for 21 or more 7650's.

*Note: For units with Model No. 7650 00XB and 7650 50X (CE-marked), do only use spare parts which are marked in the table below with a (*) or where an Issue is listed with that or a higher issue.*

Description	Part No.	Number installed		
		A (1-5)	B (6-20)	C (21+)
Case assembly	7650 0121	1		1
Case assembly rapid	7650 0126	1		1
Calibrator assembly	7650 0028	1		1
Front Panel assembly	7650 0124	1		1
Front Panel assembly rapid	7650 0127	1		1
Hood assembly	7650 0122	1		1
Sensor Spool assembly	7650 0123	1		1
Main PCB assembly	7650 0811	1		1
Power supply assembly	7650 0812	1		1
Display PCB assembly	7650 0814	1		1
Floating PCB assembly	* 7650 0817	1		1
Floating Screen assembly	* 7650 0034B	1		1
Inner can cover assembly	* 7650 0039B	1		1
Inner can case	* 7650 0254	1		1
Insulating Sleeve assembly	7650 0032		1	
Touch Panel assembly	7650 0125	1		1
Prom Mainboard	7650 0401	Hold as Master Copy when needed		
Prom Floatingboard	7650 0404	Hold as Master Copy when needed		
Prom Mainboard (rapid version)	7650 0408	Hold as Master Copy when needed		
Prom Mainboard USA (rapid version)	7650 0412	Hold as Master Copy when needed		
Prom Floatingboard (rapid version)	7650 0409	Hold as Master Copy when needed		
GAL Mainboard	7650 0402	Hold as Master Copy when needed		
GAL Mainboard	7650 0403	Hold as Master Copy when needed		
GAL Floatingboard	7650 0405	Hold as Master Copy when needed		
GAL Floatingboard (rapid version)	7650 0410	Hold as Master Copy when needed		
Battery	069 005	1		1
Battery Holder assembly	7650 0027		1	
Mains Inlet assy	7650 0053		1	
DC-Connector assembly EMC	7650 0083		1	
Loudspeaker assy	7650 0056	1		1
Mains transformer 240V/18V	031 003		1	
Isolation Transformer	7650 0051	1		1
Input socket assembly	* 7650 0057B	1	1	1
Monitor on/off switch assembly	7650 0055	1		1
LCD – Module DCM 16202	064 038	1		1
LED Bar TDA4100	064 019	1	1	1
7 Segm. LED Controller ICM7218	054 387	1		1
7 Segm. LED	064 039	3	6	9

Any other, not listed electrical or electromechanical component are commonplace components that could be available from your internal stock or obtainable locally.

7.3 General Assy. 7650 0120

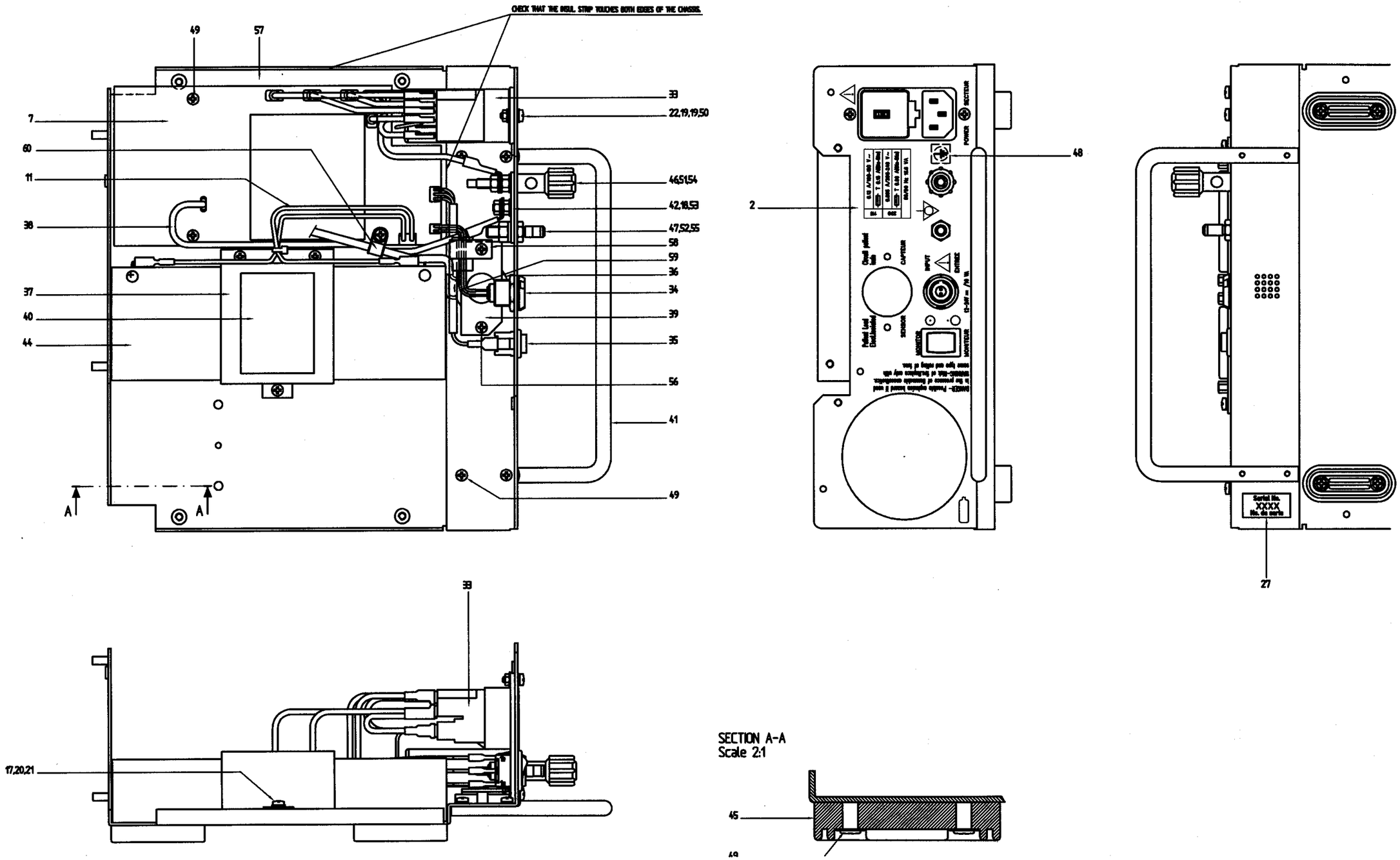
7.3.1 Parts List No. 7650 0120 Iss. 14

Item	Part No.	Qty.	Description
1			
2	7650 0204	1	Chassis silkscreened
3	7650 0028	1	Calibrator assy
4	7650 0814	1	Display board PCB assy
5	7650 0811	1	Main PCB assy
6	7650 034B	1	Floating screeen assy
7	7650 0812	1	Power supply PCB assy
8	7650 0061	1	Cable form assy, Main - p.s.
9	7650 0062	1	Cable form assy, Main - floating
10	7650 0063	1	Cable form assy, Main - display
11	7650 0065	1	Cable form assy, Battery - p.s.
12	7650 0066	1	Cable form assy, Touchp - display
13	7650 0231	4	Spring
14	7650 0225	2	Tie bar
15	702 218	4	Pcb FxG clip (moulding)
16			
17	008 322	28	Pan head screw M3 x 8DIN 85A, steel zinc plate blue
18	008 047	8	Serrated lock washer for M4, DIN 6798A, spring steel / zinc plate blue
19	008 033	17	Serrated lock washer for M3 DIN 6798A spring steel / zinc plate blue
20	008 031	25	Washer for M3 DIN 125A, Stainless steel A2
21	008 034	17	Spring washer for M3 DIN 137A, Stainless steel 1.4310
22	008 030	6	Hexagon nut ~ 0,80 M3 DIN 934, Steel 8 / zinc plate blue
23			
24	7650 0224	1	Mains inlet insul.
25	077 103	1	O-Ring seal Æ 23 x 3 silicone
26			
27	7650 0326	1	Serial No. Label
28	7650 0408 7650 0412	1	EPROM (U5 Mainboard) rapid EPROM (U5 Mainboard) rapid USA
29	7650 0402	1	GAL (U17 Mainboard)
30	7650 0403	1	GAL (U18 Mainboard)
31	7650 0409	1	EPROM (U6 Floating Board) rapid
32	7650 0410	1	GAL (U4 Floating Board) rapid
33	7650 0053	1	Mains inlet assy.
34	7650 0083	1	DC connector assy. EMC
35	7650 0055	1	Monitor On/Off switch assy.
36	7650 0056	1	Loudspeaker assy.
37	7650 0027	1	Battery holder assy.
38	7650 0064	1	Cable form assy. earth
39	7650 0076	1	Loudspeaker holder assy.
40	7650 0327	1	Battery installation label
41	7650 0210	1	Protection handle
42	7650 250	1	Earth plate
43			
44	069 005	1	Battery 12V 1,9Ah
45	702 219	4	Foot moulding
46	004 324	1	Eq. pot. ground L1361/1
47	004 322	1	Eq. pot. ground, Terminal MC-PDAG-S6/15
48	105 235	1	Earth label
49	008 321	22	Linsenschraube eco-fix M3x6
50	008 323	2	Pan head screw M3x10 DIN 85A, steel, zinc plate blue
51	008 053	2	Serrated lock washer for M5, DIN 6798A Spring steel / zinc plate blue
52	008 008	1	Serrated lock washer for M6, DIN 6798A Spring steel / zinc plate blue

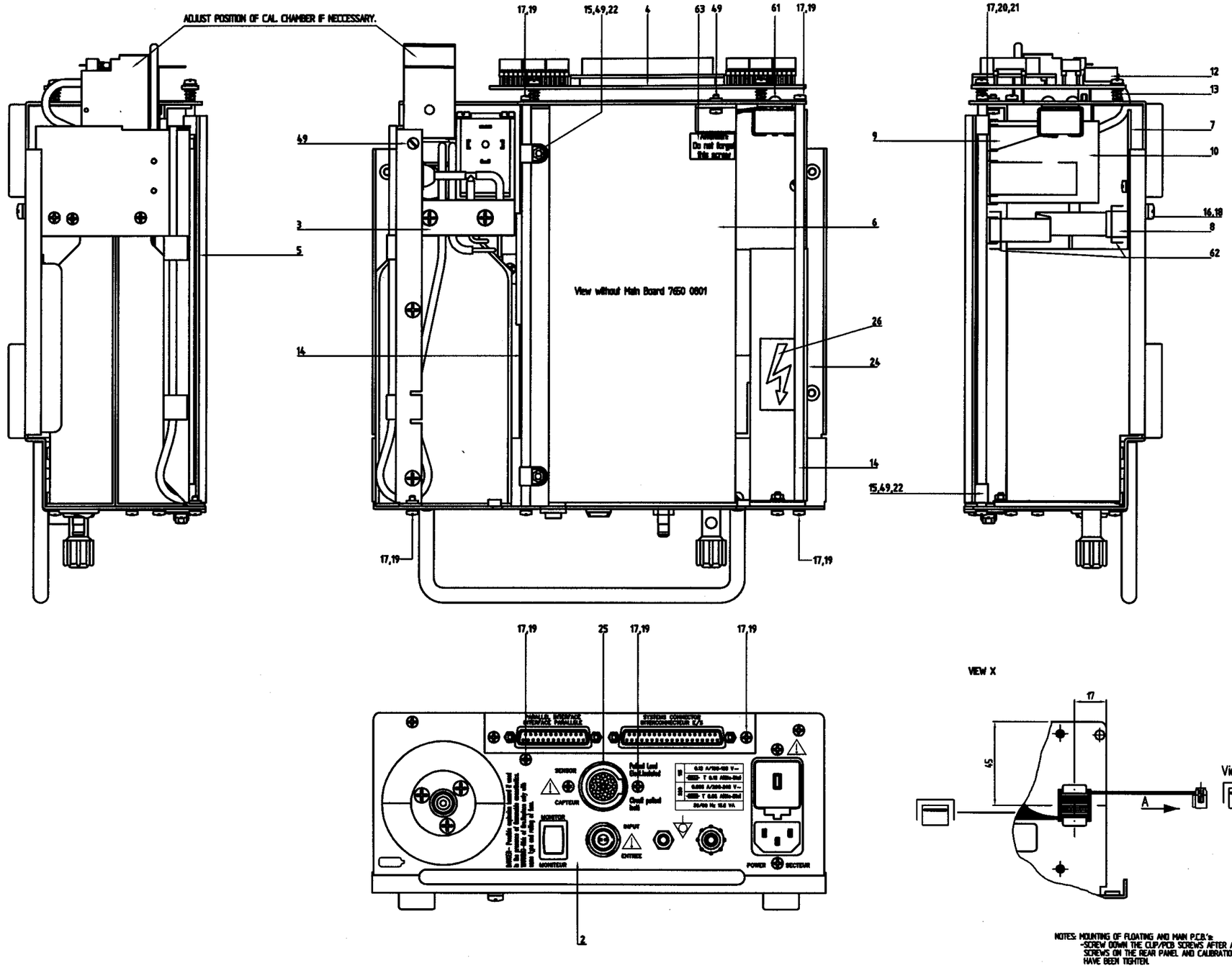
Item	Part No.	Qty.	Description
53	008 039	2	Hexagon nut ~0,8D, M4 DIN 439B, steel 04 / zinc plate blue
54	008 009	2	Hexagon nut, 2BA, nickel plated
55	008 011	1	Hexagon nut ~0,8D, M6 DIN 934, steel 8 / zinc plate blue
56	---	2	Linsenschraube eco-fix M3x8
57	7650 0243	1	Chassis insul. strip.
58	---	1	Befestigungsschelle H6P
59	7650 0257	1	PVC Ring
60	---	1	Cable Clamp
61	---	2	Spreizniete SPREIKO ø3 x 5.5
62	---	4	Verriegelungsbügel kurz
63	500.84.011	1	Screw Warning Label

7.3.2 Drawing No. 7650 0120 Iss. 11

sheet 1 / 2



sheet 2 / 2


ADJUST POSITION OF CAL. CHAMBER IF NECESSARY.
17,19
15,49,22
4
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17,19
17,20,21
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16,18
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62
9
6
49
3
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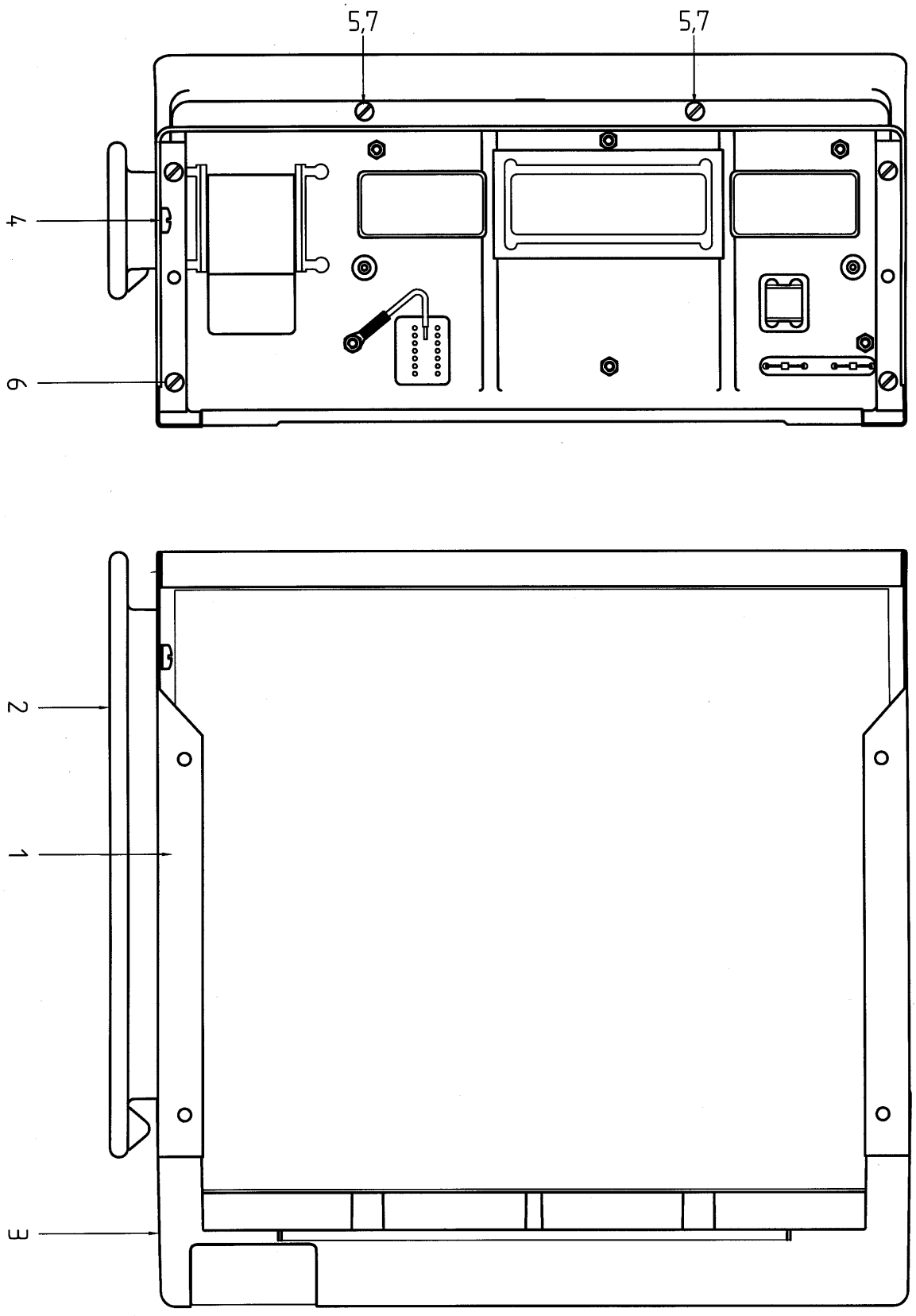
14
26
24
View without Main Board 7650 0801
14
15,49,22
17,19
17,19
17,19
25
17,19
17,19
2
VIEW X
17
45
62
View A
A
NOTES: MOUNTING OF FLOATING AND MAIN P.C.B.'s:
-SCREW DOWN THE CLIP/PCB SCREWS AFTER ALL OTHER
SCREWS ON THE REAR PANEL AND CALIBRATION UNIT
HAVE BEEN TIGHTEN.

7.4 Case Assy. 7650 0121

7.4.1 Parts List No. 7650 0121 Iss. 4

Item	Part No.	Qty.	Description
1	7650 0122	1	Hood assy.
2	7650 0123	1	Sensor spool assy
3	7650 0124	1	Front panel assy
4	---	2	Linsenschraube eco-fix M4x8
5	008 321	2	Screw M3x6 Positiv DIN 7985A, steel zinc plate blue
6	---	4	Linsenschraube eco-fix M3x6
7	008 033	2	Serrated lock washer for M3 DIN 67987A, spring steel, zinc plate blue

7.4.2 Drawing No. 7650 0121 Iss. 4

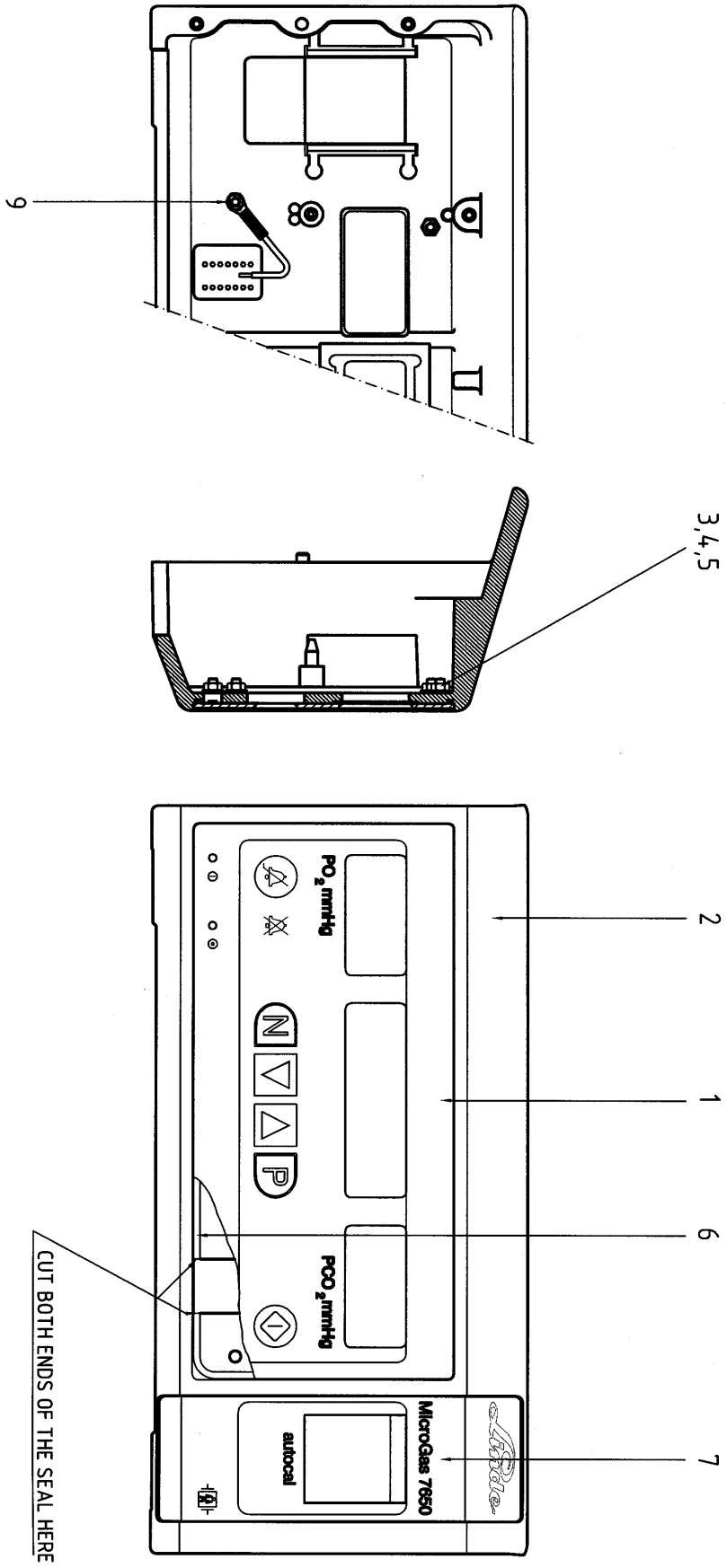


7.5 Front Panel Assy. 7650 0124

7.5.1 Parts List No. 7650 0124 Iss. 3

Item	Part No.	Qty.	Description
1	7650 0125	1	Touch panel assy
2	7650 0300	1	Front panel moulding
3	008 030	6	Hexagon nuts ~0.8D M3 DIN 934, steel 8, zinc plate blue
4	008 031	6	Washer for M3 DIN 125A, stainless steel A2
5	008 034	6	Spring washer for M3 DIN 137A, stainless steel 1.4310
6	008 198	A/R	Conductive seal
7	7650 0303	1	Front label
8	008 711	A/R	Loctite 496
9	7650 0068	1	Cable form assy, Touch panel-F/P

7.5.2 Drawing No. 7650 0124 Iss. 3



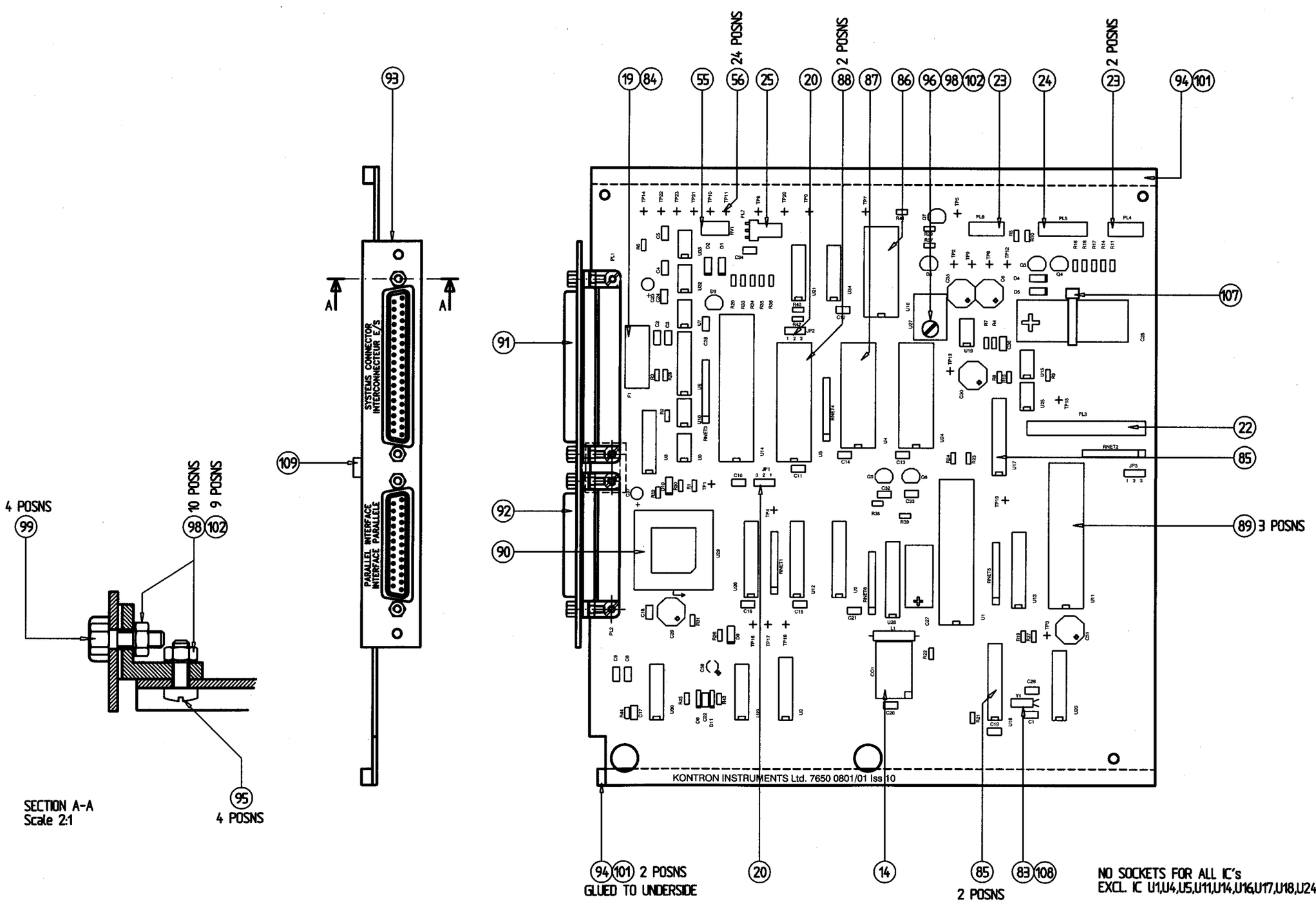
7.6 Main PCB Assy. 7650 0811

7.6.1 Parts List No. 7650 0811 Iss. 14

Item	Part No.	Qty.	Description/Part	Reference
1	022007	2	CAP 2% 100V 12pF	C8,C9
2	022010	2	CAP 5% 63V 22pF	C1,C26
3	022012	1	CAP 2% 100V 33pF	C28
4	022042	3	CAP 2% 100V 270pF	C32,C33,C36
5	022090	2	CAP 10% 63V 470pF	C2,C3
6	026028	1	CAP 10% 63V 10nF	C34
7	003089	16	CAP 20% 63V 100n	C4,C5,C10 to C22,C24
8	003184	1	TANT 20% 25V 1µF	C30
9	003191	1	TANT 20% 10V 4µ7	C37
10	003195	5	TANT 20% 16V 10µF	C6,C23,C29,C35,C38
11	003208	1	TANT 20% 16V 47µF	C31
12	021054	1	ELKO 20% 16V AXIAL 330µF	C27
13	021075	1	ELKO 20% 16V AXIAL 3300µF	C25
14	049012	1	OSZI 4.915MHZ NCC-060C4.915	CO1
15	056075	7	DIODE 1N4448	D1,D2,D4,D5,D6,D10,D11
16	056008	1	REGULATOR LM336	D3
17	056058	1	DIODE SCHOTTKY 11DQ04	D9
18	056038	1	DIODE ZENER LM385Z-2.5	D8
19	004589	1	FUSE T 0.315A	F1
20	700305	3	BERG 1*3 Units/Service/Alarm	JP1,JP2,JP3
21	038194	1	EMC AXIAL FERRITE	L1
22	072661	1	BERG 2*17 Keyboard/Display	PL3
23	072665	2	BERG 2*5 Floatingboard/PSU	PL4,PL6
24	072666	1	BERG 2*7 Calibrator	PL5
25	072508	1	MOLEX 1*3 90° Speaker	PL7
26	055017	2	TRANS SI PNP ZTX750	Q3,Q4
27	005182	1	TRANS SI NPN BC182	Q7
28	005304	2	VMOSTRANS VN10KM	Q5,Q6
29	004959	1	Jumper 0E	R23
30	001042	3	RES 1/4W 5% 56E	R33,R34,R35
31	001045	1	RES 1/4W 5% 75E	R11
32	001048	1	RES 1/4W 5% 100E	R36
33	001610	3	RES 1/4W 1% 221E	R14,R16,R26
34	001072	2	RES 1/4W 5% 1K	R2,R3
35	001726	1	RES 1/4W 1% 2K21	R32
36	001083	2	RES 1/4W 5% 3K	R6,R42
37	001088	7	RES 1/4W 5% 4K7	R21,R22,R24,R30,R31,R40,R44
38	001096	1	RES 1/4W 5% 10K	R41
39	013114	1	RES 1/4W 0.1% 12K00	R8
40	001813	1	RES 1/4W 1% 12K1	R27
41	013124	1	RES 1/4W 0.1% 14K22	R15
42	001110	2	RES 1/4W 5% 39K	R1,R25
43	001114	1	RES 1/4W 5% 56K	R37
44	013134	2	RES 1/4W 0.1% 75K00	R5,R10
45	001911	1	RES 1/4W 1% 90K9	R19
46	013148	1	RES 1/4W 0.1% 82K5	R7
47	001120	4	RES 1/4W 5% 100K	R17,R18,R38,R39
48	001922	1	RES 1/4W 1% 115K	R20
49	013136	2	RES 1/4W 0.1% 150K0	R4,R9
50	001944	1	RES 1/4W 1% 182K	R29
51	001971	1	RES 1/4W 1% 316K	R28
52	019016	6	RES SIL 4K7	RNET1 to RNET6
54	001983	1	RES 1/4W 1% 392K	R43

Item	Part No.	Qty.	Description/Part	Reference
55	018406	1	RES TRIM 10K	RV1
56	004951	24	TESTPIN, TESTPOINTS H-2088	TP0 to TP23
57	054034	1	PROCESSOR 80C88-2	U1
58	053222	1	IC HCMOS 74HC245	U2
59	054410	1	IC uP Sup. MAX695	U3
60	054376	2	IC CMOS RAM HM62256	U4,U24
62	054346	1	IC DAC AD7533L	U6
63	051078	1	IC OP AMP AD648	U7
64	051110	1	IC DRIVER OC ULN2004A	U8
65	052031	1	IC RS423 TX UA9636	U9
66	052030	1	IC RS423 RX UA9637	U10
67	052113	2	IC PIO AND RAM 82C55	U11,U14
68	052623	3	IC HCMOS 74HC574	U12,U13,U28
69	052110	1	IC TIMER 82C54	U16
71	051033	1	IC VOLTAGE CONV. SI 7661	U19
72	054331	1	IC CLOCK MSM6242K	U20
73	053007	1	IC HEX BUFFER 7407	U21
74	053112	1	IC HCMOS INVERTER 74HC14	U23
75	051134	1	IC COMPERATOR LM393AN	U25
76	053319	1	IC HCMOS 74HC573	U26
77	051092	1	VOLTAGE REG. LM2940C-12	U27
78	054409	1	IC DUART VL16C452	U29
79	053024	1	IC HCMOS 74HC32	U30
80	007744	2	IC S/H LF398	U32,U33
81	052035	1	IC HCMOS 74HC132	U34
82	051066	1	IC OP AMP LM11CN	U15
83	004521	1	QUARZ 32.768KHz	Y1
84	074026	1	20mm Fuse MTG ClipD/END 5229	F1
85	072055	2	SKT 20W LOW PROFILE TIN	U17,U18
86	004297	1	SKT 24W LOW PROFILE TIN	U16
87	072054	2	SKT 28W LOW PROFILE TIN	U4,U24
88	072530	1	SKT 32W LOW PROFILE TIN	U5
89	072052	3	SKT 40W LOW PROFILE TIN	U1,U11,U14
90	072060	1	SKT 68W/4SIDE 2ROW	U29
91	072252	1	D-SUB 37+BRKT Kontron Interface	PL1
92	072251	1	D-SUB 25+BRKT Parallel Port	PL2
93	7650 0233	1	Interface Plate Silkscreened	-
94	7650 0229	2	Guard Profil	-
95	008322	4	Screw M3x8 DIN 85A St.4.8/Zinc Plate	-
96	008321	1	Screw M3x6 DIN 85A St.4.8/Zinc Plate	-
98	008034	10	Crinkle Washer for M3 DIN 137A 1.4310	-
99	7650 0255	4	Jack Pin M3	-
101	008153	A/R	Tape 4970 6mm Wide, Double Sided TESAFIX	-
102	008030	9	St.8/Zinc Plate Hex. Nut 0.8 M3 DIN 934	-
104	7650 0801	1	PCB	-
107	004975	1	Ty-Rap T18R	-
108	008150	A/R	Double Sided Adesive Tape	-
109	7650 0355	1	Abschirmfeder (screening spring)	-

7.6.2 Drawing No. 7650 0811 Iss. 11



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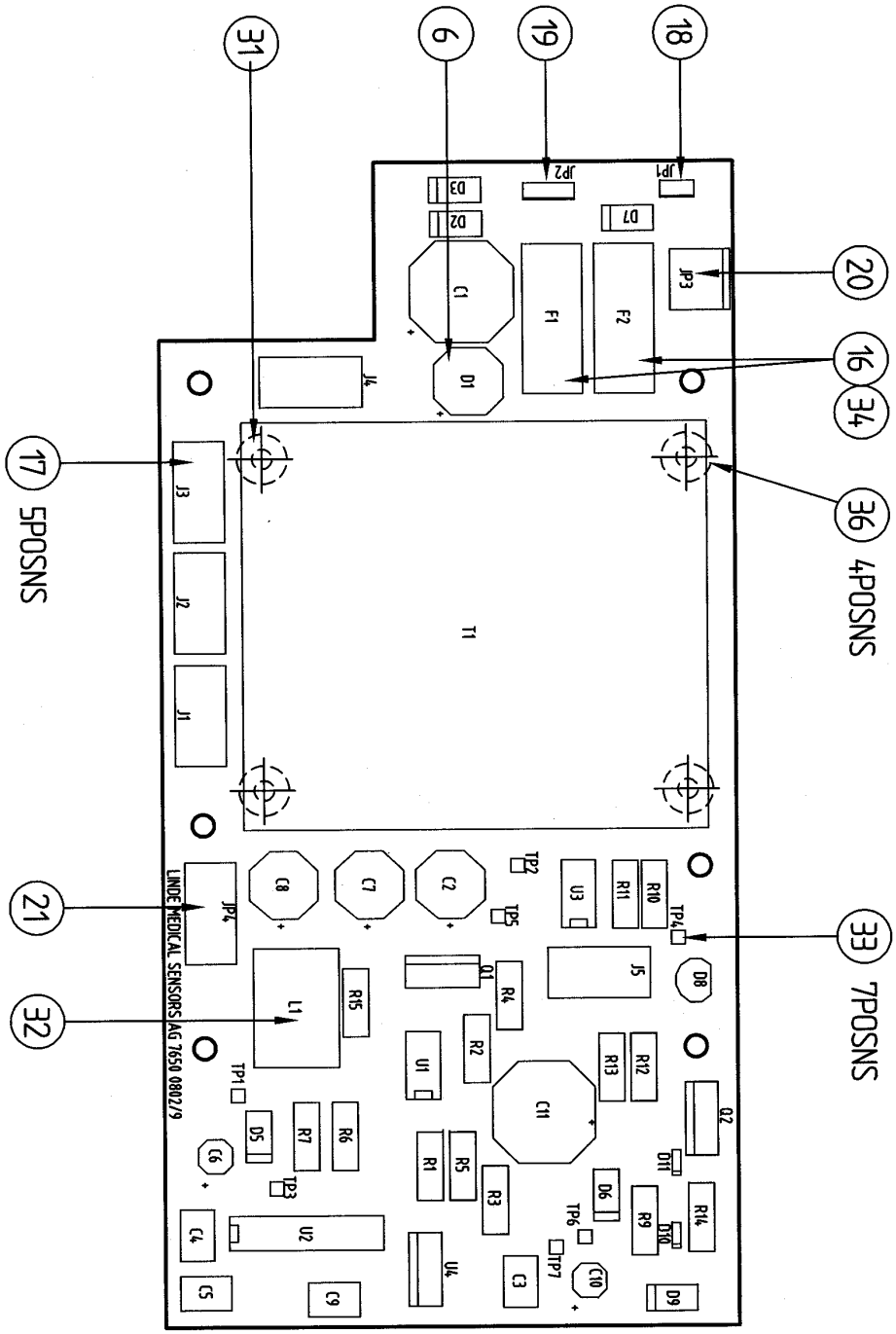
7.7 Power Supply PCB Assy. 7650 0812

7.7.1 Parts List No. 7650 0812 Iss. 10

Item	Part No.	Qty.	Description/Part	Reference
1	026031	1	CAP MKT 10% 50V 1µF	C3
2	003089	1	CAP CER 20% 63V 100n	C9
3	003224	1	TANT 25V 20% 10µF	C10
4	003448	3	ELKO 35V 20% RAD 220µF	C2,C7,C8
5	021004	2	ELKO 35V 20% RAD 1000µF	C1,C11
6	057016	1	BRIDGE RECTIF. B40C1500	D1
7	004991	2	DIODE 1N4001	D6,D9
8	056058	4	DIODE SCHOTTKY 11D04	D2,D3,D5,D7
9	054343	1	VOLT REF. TL431	D8
10	056075	2	DIODE 1N4448	D10,D11
11	055046	1	MOS POWER FET RFP8P08	Q1
12	005135	1	POWER TRANS. BD135	Q2
13	007703	1	VOLTAGE COMPERATOR LM311	U1
14	007741	1	OP-AMP LM741	U3
15	051094	1	SWITCH-MODE REG. 5V LM2575	U4
16	074007	2	FUSE 1A	F1,F2
17	073045	5	AMP-TABS AMP1	J1 to J5
18	072305	1	MOLEX 1x2 P 0,1" FROM BATERY EXT.	JP1
19	072306	1	MOLEX 1x3 P 0,1" FROM MAINSWITCH	JP2
20	072715	1	MOLEX 1x2 (5281) TO BATTERY	JP3
21	072665	1	BERG 2x5 TO MAINBOARD	JP4
22	002309	1	RES. 1/2W 5% 6E8	R14
23	001679	1	RES. MF 1/4W 1% 825	R13
24	001766	1	RES. MF 1/4W 1% 4k75	R12
25	001786	2	RES. MF 1/4W 1% 6k81	R1,R10
26	001804	1	RES. MF 1/4W 1%10k0	R3
27	001835	2	RES. MF 1/4W 1% 20k0	R2,R4
28	001856	1	RES. MF 1/4W 1% 30k1	R11
29	001928	1	RES. MF 1/4W 1% 130k	R9
30	001953	1	RES. MF 1/4W 1% 221k	R5
31	031003	1	TRANSFORMER 240V/18V TRANSF.MAINS	T1
32	034011	1	INDUCT. DSH 1-22-1, 0-400/A 400µH	L1
33	004951	7	TEST-PIN TP	TP1 to TP7
34	074026	2	20mm Fuse MTG Clip D/END 5229	F1,F2
35	7650 0802	1	PCB	-
36		4	Linsen Blechschrauben mit Bund 2.9 x 9.5	

7.7.2 Drawing No. 7650 0812 Iss. 9

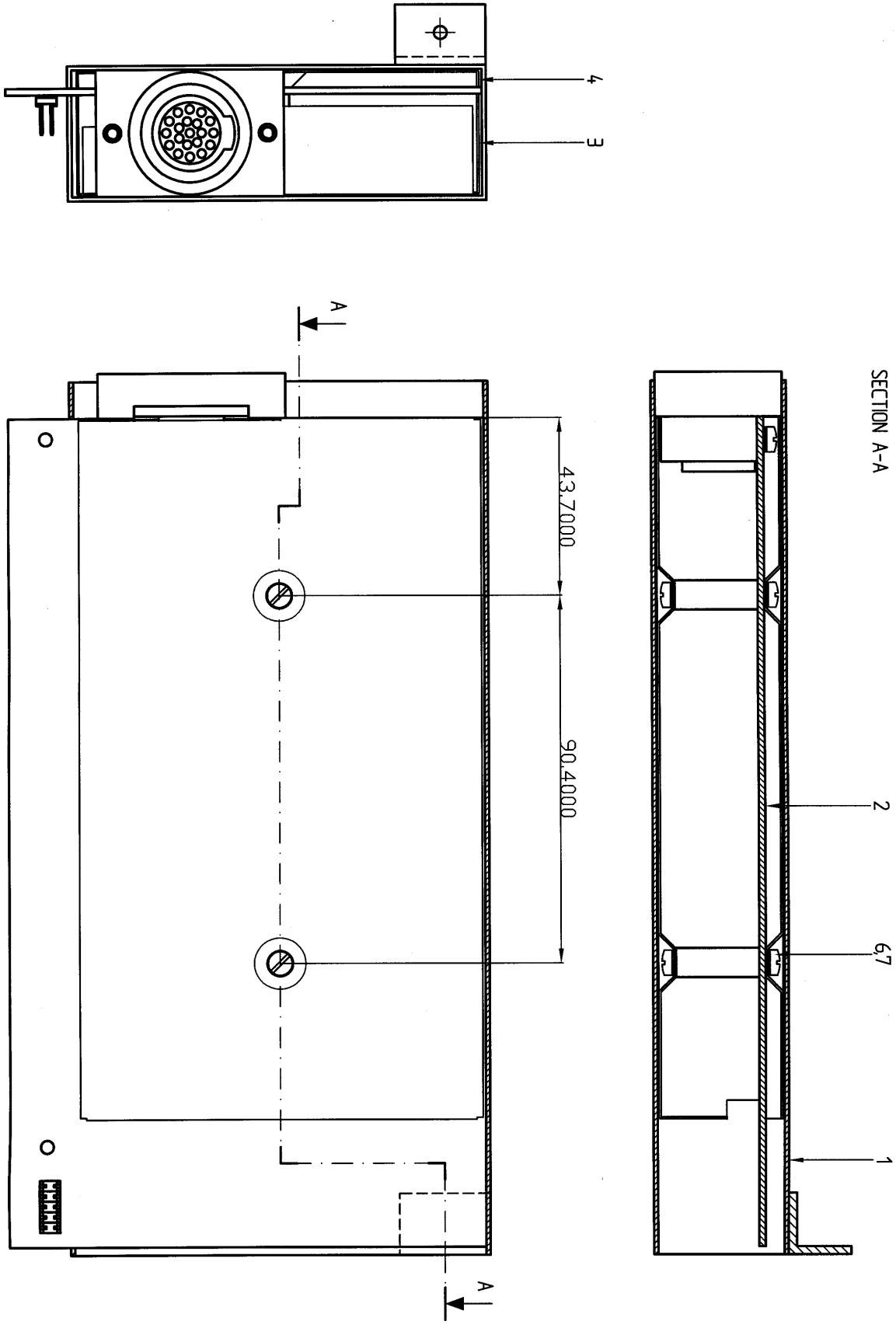


7.8 Floating Screen Assy. 7650 0034

7.8.1 Parts List No. 7650 0034 Iss. 2

Item	Part No.	Qty.	Description
1	7650 0032	1	Insul. sleeve assy
2	7650 0813	1	Floating pcb assy
3	7650 0220	1	Inner can case
4	7650 0039	1	Inner can cover assy
6	008 321	4	Pan head screw M3x6 DIN 85A, steel, zinc plate blue
7	008 031	4	Serrated lock washer for M3 DIN 6798A, spring steel, zinc plate blue

7.8.2 Drawing No. 7650 0034 Iss. 2



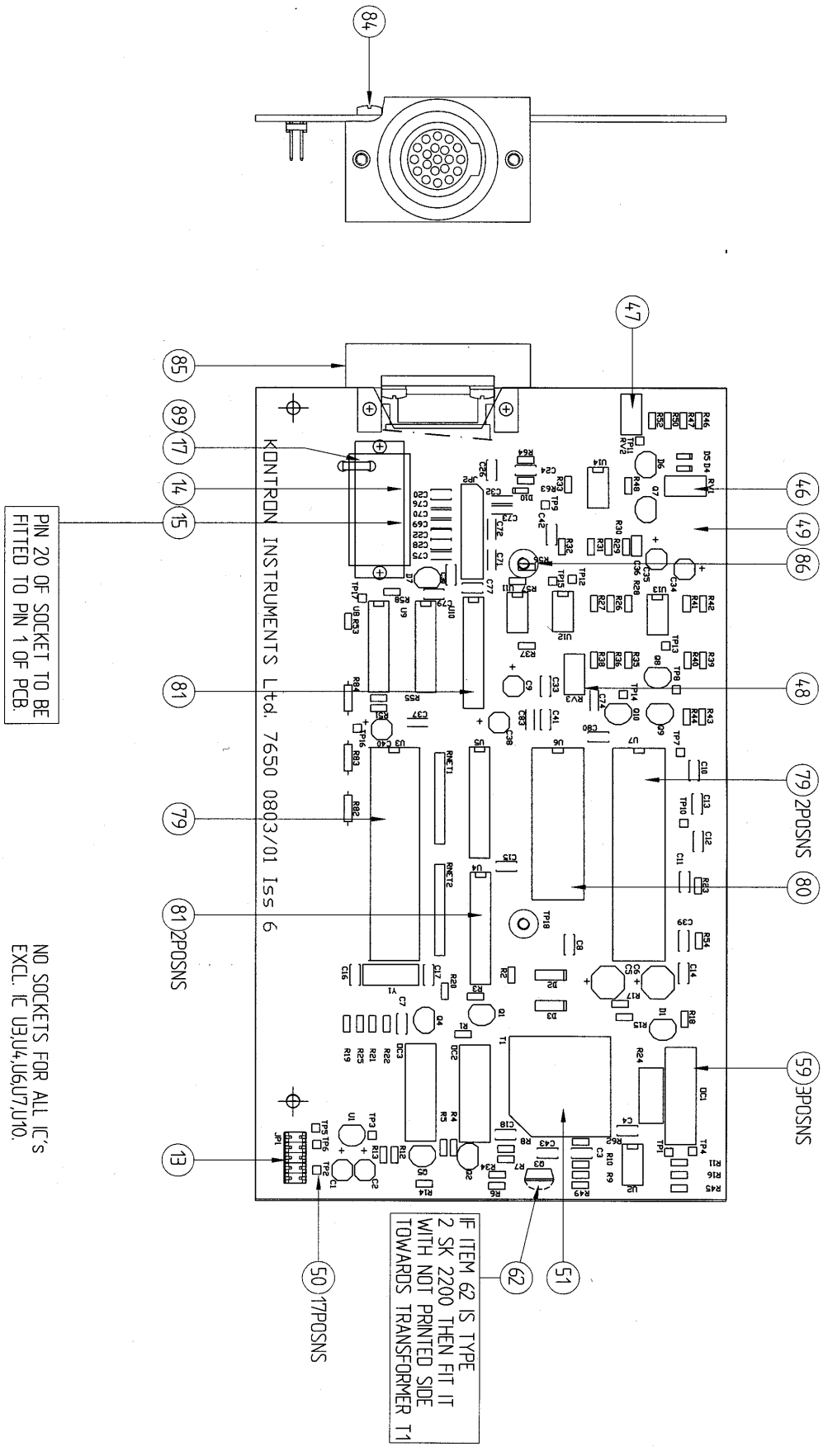
7.9 Floating PCB Assy. 7650 0813

7.9.1 Parts List No. 7650 0813 Iss. 6

Item	Part No.	Qty.	Description/Part	Reference
1	022006	2	CAP CERAMIC 100V 10pF	C16,C17
2	022010	2	CAP CERAMIC 100V 22pF	C36,C39
3	022046	2	CAP CERAMIC 100V 560pF	C7,C18
4	026043	1	CAP MKT 50V 5% 1n5	C4
5	026044	1	CAP MKT 50V 10% 2n2	C3
6	026026	17	CAP MKT 63V 10% 0.1uF	C11,C12,C14,C19 to C31,C42
7	026031	2	CAP MKT 50V 10% 1uF	C13,C33
8	003191	6	TANT 10V 20% 4u7	C8,C9,C10,C15,C40,C32
9	003195	3	TANT 16V 20% 10uF	C2,C37,C38
10	003196	2	TANT 20V 20% 15uF	C34,C35
11	003210	1	TANT 35V 20% 47uF	C1
12	021077	2	ELKO 10V 20% RAD SU-A 470uF	C5,C6
13	072665	1	BERG 5X2 HEADER 5X2	JP1
15	072596	1	20 PIN ST CONNECTOR PCB	JP3
16	004433	6	INDUCTOR 100uH	L1,L2,L3,L4,L5,L6
17	706052	1	INDUCTOR 100uH	L7
17A	001461	1	RES. MF 1/4W 1% 10R0	R39
18	001014	1	RES. CF 1/4W 5% 3E3	R34
18A	001573	2	RES. MF 1/4W 1% 100	R8,R22
19	001591	1	RES. MF 1/4W 1% 150	R10
20	001615	1	RES. MF 1/4W 1% 243	R61
21	001624	2	RES. MF 1/4W 1% 294	R1,R14
22	001679	1	RES. MF 1/4W 1% 825	R15
23	001683	1	RES. MF 1/4W 1% 909	R46
24	001804	16	RES. MF 1/4W 1% 10K	R2,R3,R6,R7,R11,R12,R13, R21,R25,R40,R44,R53,R56, R57,R58,R60
25	001822	1	RES. MF 1/4W 1% 15K	R45
26	001688	6	RES. MF 1/4W 1% 1K	R4,R5,R9,R19,R20,R38
27	001770	3	RES. MF 1/4W 1% 5K11	R17,R18,R43
28	001786	2	RES. MF 1/4W 1% 6K81	R16,R59
29	001831	1	RES. MF 1/4W 1% 18K2	R55
30	001856	1	RES. MF 1/4W 1% 30k1	R49
31	001898	2	RES. MF 1/4W 1% 68K1	R35,R36
32	001992	1	RES. MF 1/4W 1% 475K	R42
33	011941	1	RES. 1/4W 5% 22M	R41
34	011942	1	RESISTOR 1G	R24
35	001916	3	RES. MF 1/4W 1% 100K	R23,R51,R54
36	001964	3	RES. MF 1/4W 1% 274K	R26,R30,R37
37	013105	1	RES. MF 0.1% 30*	R33
38	013106	1	RES. MF 0.1% 400*	R32
39	013110	1	RES. MF 1/4W 0.1% 4K*	R48
40	013111	1	RES. MF 1/4W 0.1% 5K*	R47
41	013112	1	RES. MF 0.1% 5K403*	R31
42	013114	1	RES. MF 0.1% 12K*	R29
43	013104	2	RES. MF 0.05% 12K**	R27,R28
44	013210	1	RES. MF 15ppm 909#	R50
45	013211	1	RES. MF 15 ppm 1k3#	R52
46	018406	1	POT CMT 20TN 10% VM 10K	RV1
47	018466	1	POT CMT 20TN 10% VM 100	RV2
48	018409	1	POT CMT 20TN 10% VM 50K	RV3
49	045015	1	RELAY V23026-A1	RL1
50	76500051	1	TRANSFORMER ASSY	T1

Item	Part No.	Qty.	Description/Part	Reference
51	004951	17	TEST - PIN TP	TP1 to TP17
52	054343	1	VOLT. REF. TL431	D1
53	056058	2	DIODE SCHOTTKY 11DQ04	D2,D3
54	056075	3	DIODE 1N4448	D4,D5,D9
55	056008	1	VOLT. REF. LM336	D6
56	056039	1	VOLT. REF. LM385-1.2	D7
57	005036	1	DIODE ZENER 1/2W BZX79F3V6	D8
58	056041	1	DIODE 6V2 ZENER LOW I T-LVA462	D10
59	054352	3	OPTO-COUPL. OPI1264A	OC1,OC2,OC3
60	005212	5	TRANS. PNP BC212	Q1,Q5,Q6,Q7,Q10
61	005182	2	TRANS. NPN BC182	Q2,Q4
62	054388	1	TRANS. FET 2N7010 or 2SK1113 or 2SK2200	Q3
63	055017	1	TRANS. PNP ZTX750	Q8
64	055016	1	TRANS. NPN ZTX650	Q9
65	051032	1	VOLTAGE REG. 8V 7808	U1
66	052078	1	TIMER ICM7555	U2
67	054022	1	SIGLE CHIP uP 80C32	U3
69	052623	1	LATCH 74HC574	U5
70	007733	1	OP-AMP LM308AN	U14
71	054354	1	A/D CONVERTER ICL7109	U7
72	052111	1	MUX DG508	U8
73	053116	1	74HC366	U9
74	054353	1	D/A CONVERTER DAC832	U10
75	051063	1	OP-AMP OP07	U11
76	051066	1	OP-AMP LM11	U12
77	051091	1	OP-AMP ICL7611	U13
78	049013	1	9.8304Mhz	Y1
79	072052	2	40 PIN DIL SOCKET	U3,U7
80	072054	1	28 PIN DIL SOCKET	U6
81	072055	2	20 PIN DIL SOCKET	U4,U10
82	76500803	1	PCB	
83*	76500052	1	INPUT SOCKET ASSEMBLY	
84	008340	2	SCREW No 4 x 3/8"	
85	76500057	1	INPUT SOCKET ASSEMBLY	
86	76500232	2	SUPPORT (REWORKED)	
87	022042	1	CAP MMK 100V 10% 270pF	C41
88	019004	2	RES SIL 10k	RNET1,RNET2
89	004766	A/R	Lacing Cord	

7.9.2 Drawing No. 7650 0813 Iss. 7

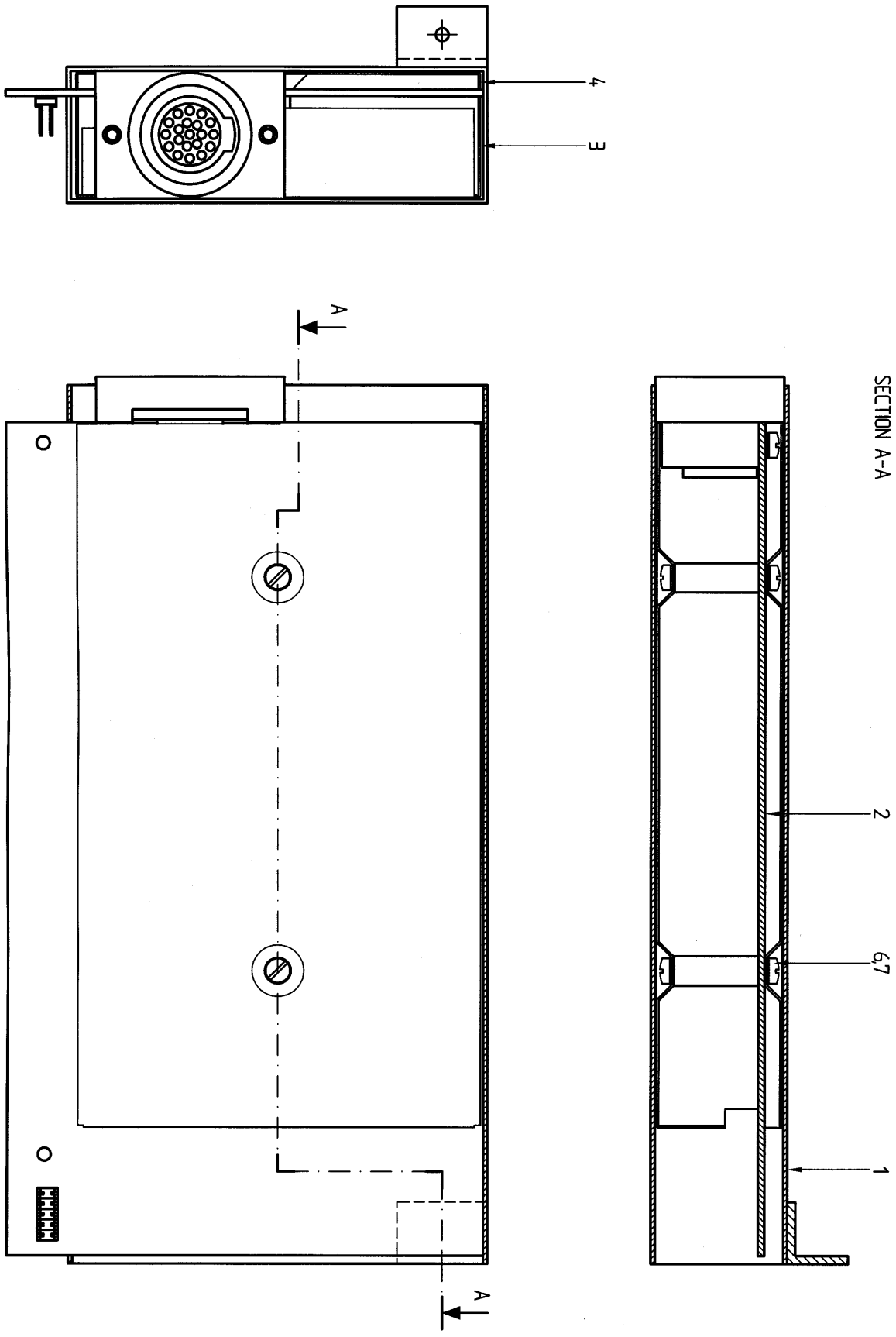


7.10 Floating Screen Assy. 7650 0034B

7.10.1 Parts List No. 7650 0034B Iss. 2

Item	Part No.	Qty.	Description
1	7650 0032	1	Insul. sleeve assy
2	7650 0817	1	Floating PCB assy
3	7650 0254	1	Inner can case
4	7650 0039B	1	Inner can cover assy
6		4	Screw M3x6 Pozidriv DIN 7985A, steel, zinc plate blue
7	008 033	4	Serrated lock washer for M3 DIN 6798A, spring steel, zinc plate blue

7.10.2 Drawing No. 7650 0034B Iss. 1



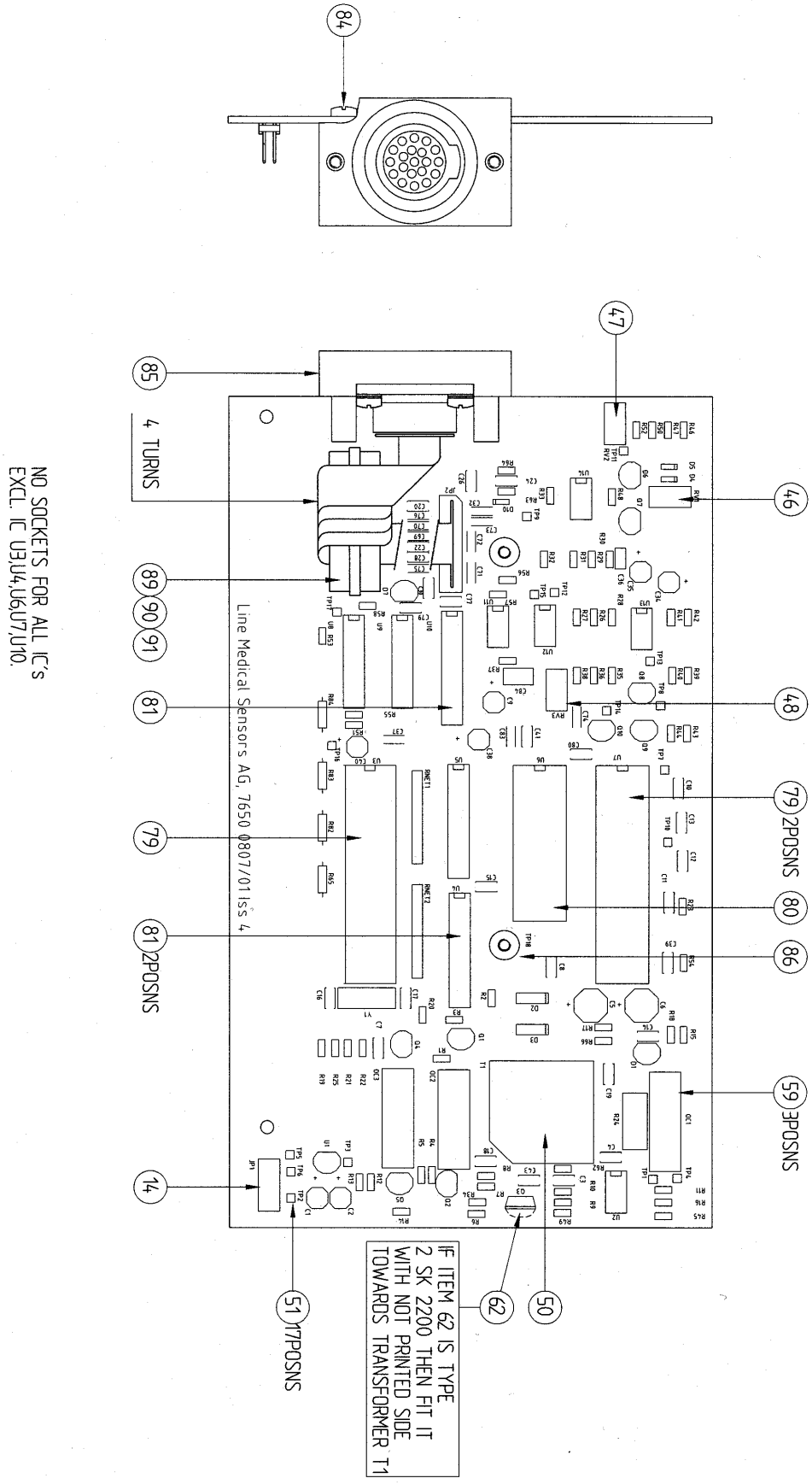
7.11 Floating PCB Assy. 7650 0817

7.11.1 Parts List No. 7650 0817 Iss. 8

Item	Part No.	Qty.	Description/Part	Reference
1	022006	2	CAP CERAMIC 100V 10pF	C16,C17
2	022010	6	CAP CERAMIC 100V 22pF	C36,C39,C69,C70,C71,C72
3	022046	2	CAP CERAMIC 100V 560pF	C7,C18
4	026043	2	CAP MKT 50V 5% 1n5	C4,C43
5	026044	1	CAP MKT 50V 10% 2n2	C3
6	026026	2	CAP MKT 63V 10% 0.1uF	C11,C12
7	026031	1	CAP MKT 50V 10% 1uF	C13
8	003191	3	TANT 10V 20% 4u7	C9,C40,C38
9	022090	3	CAP 63V 10% 470pF	C74,C75,C76
10	003196	3	TANT 20V 20% 15uF	C2,C34,C35
11	003210	1	TANT 35V 20% 47uF	C1
12	021077	2	ELKO 10V 20% RAD SU-A 470uF	C5,C6
13	003089	17	CAP 63V 20% 100nF	C8,C10,C14,C15,C20,C22, C24,C26,C28,C30,C32,C37, C73,C77,C79,C80,C83
14		1	Header Connector W10, doc. no. 232.0101.1	JP1
15	072722	1	MOLEX 52045-1610 HEADER 16	JP2
16	001461	1	RES. MF 1/4W 1% 10E0	R39
17	001014	3	RES. CF 1/4W 5% 3E3	R34,R63,R64
18	001573	2	RES. MF 1/4W 1% 100	R8,R22
19	001591	1	RES. MF 1/4W 1% 150	R10
20	001615	1	RES. MF 1/4W 1% 243	R62
21	001624	2	RES. MF 1/4W 1% 294	R1,R14
22	001679	1	RES. MF 1/4W 1% 825	R15
23	001683	1	RES. MF 1/4W 1% 909	R46
24	001804	15	RES. MF 1/4W 1% 10K	R2,R3,R6,R7,R11,R12,R13, R21,R25,R40,R44,R53,R56, R57,R58
25		1	RES. MF 1/4W 1% 8K2	R45
26	001688	6	RES. MF 1/4W 1% 1K	R4,R5,R9,R19,R20,R38
27	001770	3	RES. MF 1/4W 1% 5K11	R17,R18,R43
28		2	RES. MF 1/4W 1% 3K6	R16
29	001831	1	RES. MF 1/4W 1% 18K2	R55
30	001856	1	RES. MF 1/4W 1% 30k1	R49
31	001898	2	RES. MF 1/4W 1% 68K1	R35,R36
32	001992	1	RES. MF 1/4W 1% 475K	R42
33	011941	1	RES. 1/4W 5% 22M	R41
34	011942	1	RESISTOR 1G	R24
35	001916	3	RES. MF 1/4W 1% 100K	R23,R51,R54
36	001964	3	RES. MF 1/4W 1% 274K	R26,R30,R37
37	013105	1	RES. MF 0.1% 30*	R33
38	013106	1	RES. MF 0.1% 400*	R32
39	013110	1	RES. MF 1/4W 0.1% 4K*	R48
40	013111	1	RES. MF 1/4W 0.1% 5K*	R47
41	013112	1	RES. MF 0.1% 5K403*	R31
42	013114	1	RES. MF 0.1% 12K*	R29
43	013104	2	RES. MF 0.05% 12K**	R27,R28
44	013210	1	RES. MF 15ppm 909#	R50
45	013211	1	RES. MF 15 ppm 1k3#	R52
46	018406	1	POT CMT 20TN 10% VM 10K	RV1
47	018466	1	POT CMT 20TN 10% VM 100	RV2
48	018409	1	POT CMT 20TN 10% VM 50K	RV3

Item	Part No.	Qty.	Description/Part	Reference
49	001726	3	RES. 1/4W 1% 2k21	R82,R83,R84
50	76500051	1	TRANSFORMER RM8	T1
51	004951	17	TEST - PIN TP	TP1 to TP17
52	054343	1	VOLT. REF. TL431	D1
53	056058	2	DIODE SCHOTTKY 11DQ04	D2,D3
54	056075	2	DIODE 1N4448	D4,D5
55	056008	1	VOLT. REF. LM336	D6
56	056039	1	VOLT. REF. LM385-1.2	D7
58	056041	1	DIODE 6V2 ZENER LOW I T-LVA462	D10
59	054352	3	OPTO-COUPL. OPI1264C	OC1,OC2,OC3
60	005212	4	TRANS. PNP BC212	Q1,Q5,Q7,Q10
61	005182	2	TRANS. NPN BC182	Q2,Q4
62	054388	1	TRANS. FET RFD3055LE	Q3
63	055017	1	TRANS. PNP ZTX750	Q8
64	055016	1	TRANS. NPN ZTX650	Q9
65	051032	1	VOLTAGE REG. 8V 7808	U1
66	052078	1	TIMER ICM7555	U2
67	054022	1	SINGLE CHIP uP 80C32 conventional version	U3
68			SINGLE CHIP uP 80C528 rapid version	U3
69	052623	1	LATCH 74HC574	U5
70	007733	1	OP-AMP LM308AN	U14
71	054354	1	A/D CONVERTER ICL7109	U7
72	052111	1	MUX DG508	U8
73	053116	1	74HC366	U9
74	054353	1	D/A CONVERTER DAC832	U10
75	051063	2	OP-AMP OP07	U11,U12
76				
77	051091	1	OP-AMP ICL7611	U13
78	049013	1	9.8304Mhz	Y1
79	072052	2	40 PIN DIL SOCKET	U3,U7
80	072054	1	28 PIN DIL SOCKET	U6
81	072055	2	20 PIN DIL SOCKET	U4,U10
82	76500807	1	PCB	
84	008340	0	SCREW No 4 x 3/8"	
85	76500057B	0	INPUT SOCKET ASSEMBLY	(PART OF ASSY 7650 0059)
86	76500232	2	SUPPORT (REWORKED)	TP18
87	022042	1	CAP MMK 100V 10% 270pF	C41
88	019004	2	RES SIL 10k	RNET1,RNET2
89	038195	1	EMC FERRITE FOR FLAT FLEX	
90	004976	1	CABLE TIE 140mm	
91	008150	A/R	ADHESIVE TAPE DS 12mm	
92	022105	1	CAP CER 50V 10% 220nF	C84
93		1	RES. MF ¼W 1% 22k	R65
94		1	RES. MF ¼W 1% 4K7	R66
95	026031	1	CAP MKT 50V 10% 1µF	C19 not mounted

7.11.2 Drawing No. 7650 0817 Iss. 4

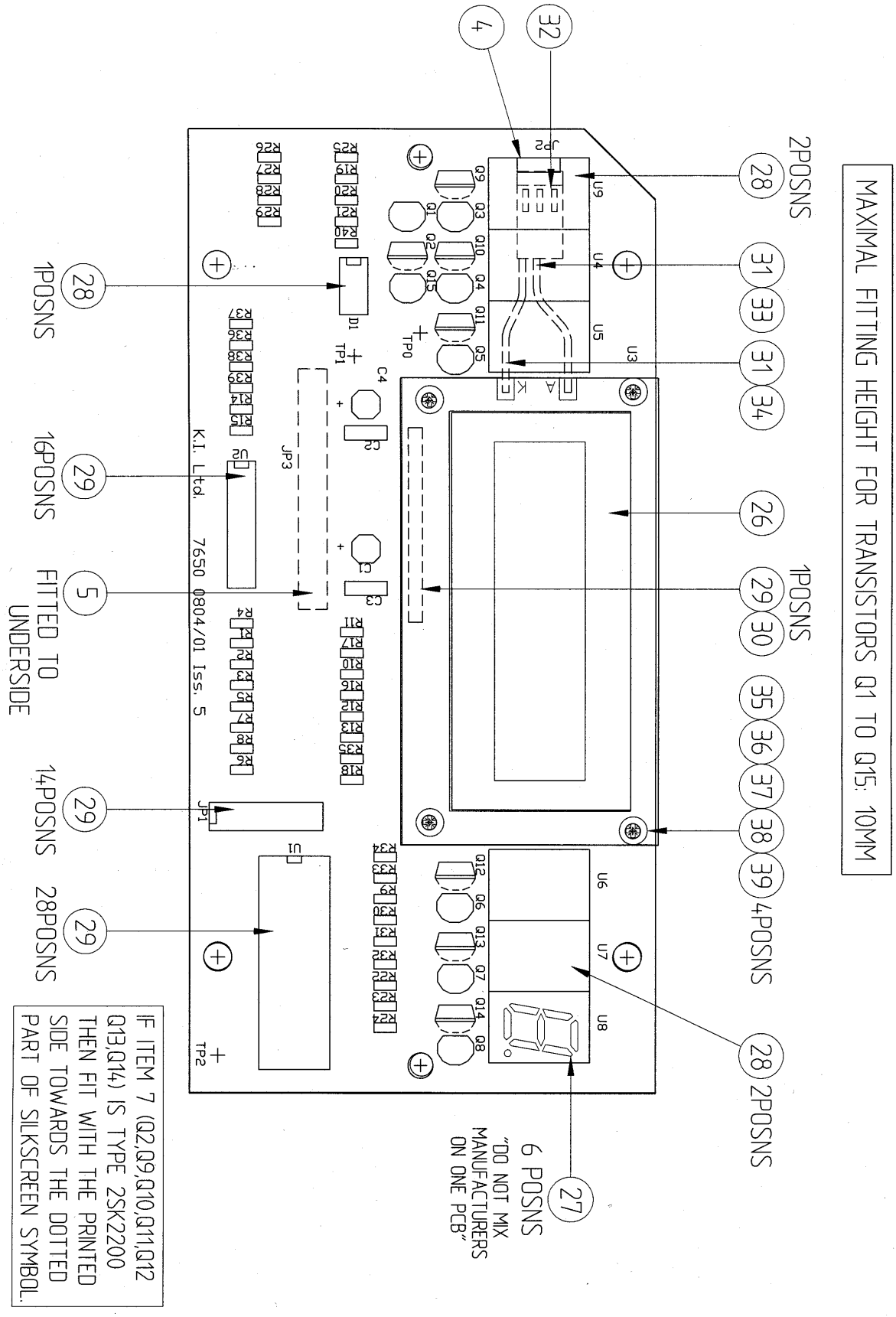


7.12 Display PCB Assy. 7650 0814

7.12.1 Parts List No. 7650 0814 Iss. 5

Item	Part No.	Qty.	Description/Part	Reference
1	003195	2	TANT 20% 16V 10uF	C1,C4
2	026026	2	CAP 10% 63V 100nF	C2,C3
3	064019	1	LED Telefunken TDA4100	D1
4	072711	1	Berg Header 3x1 90° HEADER 3	JP2
5	072661	1	Berg Header 2x17 BERG 2X17	JP3
6	005222	1	TRANS PNP BC212	Q1
7	054388	7	MOS FET 2N7010 or 2SK1113 or 2SK2200	Q2,Q9 to Q14
8	005182	7	TRANS NPN BC182	Q3 to Q8,Q15
9	001024	12	RES 1/4W 5% 10E	R10 to R18,R35,R38,R39
10	001030	1	RES 1/4W 5% 18E	R36
11	001072	2	RES 1/4W 5% 1K	R34,R37
12	001752	1	MF 1/4W 1% 3K65	R9
13	001756	1	MF 1/4W 1% 3K92	R1
14	001761	1	MF 1/4W 1% 4K32	R2
15	001770	1	MF 1/4W 1% 5K11	R3
16	001775	2	MF 1/4W 1% 5K62	R4,R33
17	001780	1	MF 1/4W 1% 6K19	R5
18	001786	1	MF 1/4W 1% 6K81	R6
19	001790	1	MF 1/4W 1% 7K50	R7
20	001795	1	MF 8K25	R8
21	001096	7	RES 1/4W 5% 10K	R26 to R32
22	001106	8	RES 1/4W 5% 27K	R19 to R25,R40
23	004951	3	TEST-POINT GND,VCC,VEE	TP0,TP1,TP2
24	054387	1	LED DRIVER ICM7218 BIPI	U1
25	006771	1	MUX 4051	U2
26	064038	1	LCD MODUL OPTREX DMC16202	U3
27	064039	6	7-Segment LED LTS547A	U4 to U9
28	072581	5	SLC TLA31 PRECICONTACT	U4 to U9,D1
29	073086	56	HARWIN SOCKED H3153-01	U1,U3,JP1
30	072543	1	SSH GH-CC PRECICONTACT	U3
31	073003	2	BERG CRIMP TO WIRE MINI PV	JP2
32	072583	1	BERG MINI LATCH HOUSING	JP2
33	004826	0.05	WIRE 0.025 RED	JP2
34	004824	0.05	WIRE 0.025 BLACK	JP2
35	76500222	4	DISTANCE SLEEVE 5mm	U3
36	008223	4	PAN HEAD SCREW M2.5x10 DIN 85A ST.8 vzp.	U3
37	008020	4	HEXAGON NUT 0.8 M2.5 DIN 934 ST.8 vzp.	U3
38	008021	4	WASHER FOR M2.5 DIN 125A STAINLESS ST.A2	U3
39	008024	4	SPRING WASHER FOR M2.5 DIN 137A ST.1.4310	
40	76500804	1	PCB	

7.12.2 Drawing No. 7650 0814 Iss. 7


MAXIMAL FITTING HEIGHT FOR TRANSISTORS Q1 TO Q15: 10MM
2POSNS
1POSNS
4POSNS
2POSNS
6 POSNS
"DO NOT MIX MANUFACTURERS ON ONE PCB"
1POSNS
16POSNS
FITTED TO UNDERSIDE
14POSNS
28POSNS
K.I. Ltd. 7650 0804/01 Iss. 5
IF ITEM 7 (Q2,Q9,Q10,Q11,Q12 Q13,Q14) IS TYPE 2SK2200 THEN FIT WITH THE PRINTED SIDE TOWARDS THE DOTTED PART OF SILKSCREEN SYMBOL.

8 Engineering Service Information

8.1 Introduction

The information given in this service manual covers the most recent modifications to the equipment, up to the date of issue. The modification status to which this manual has been prepared is detailed below.

This section provides a place for Engineering Service Information Bulletins (ESI's) issued after publication of this service manual. Information from previously issued ESI's has been incorporated into the manual.

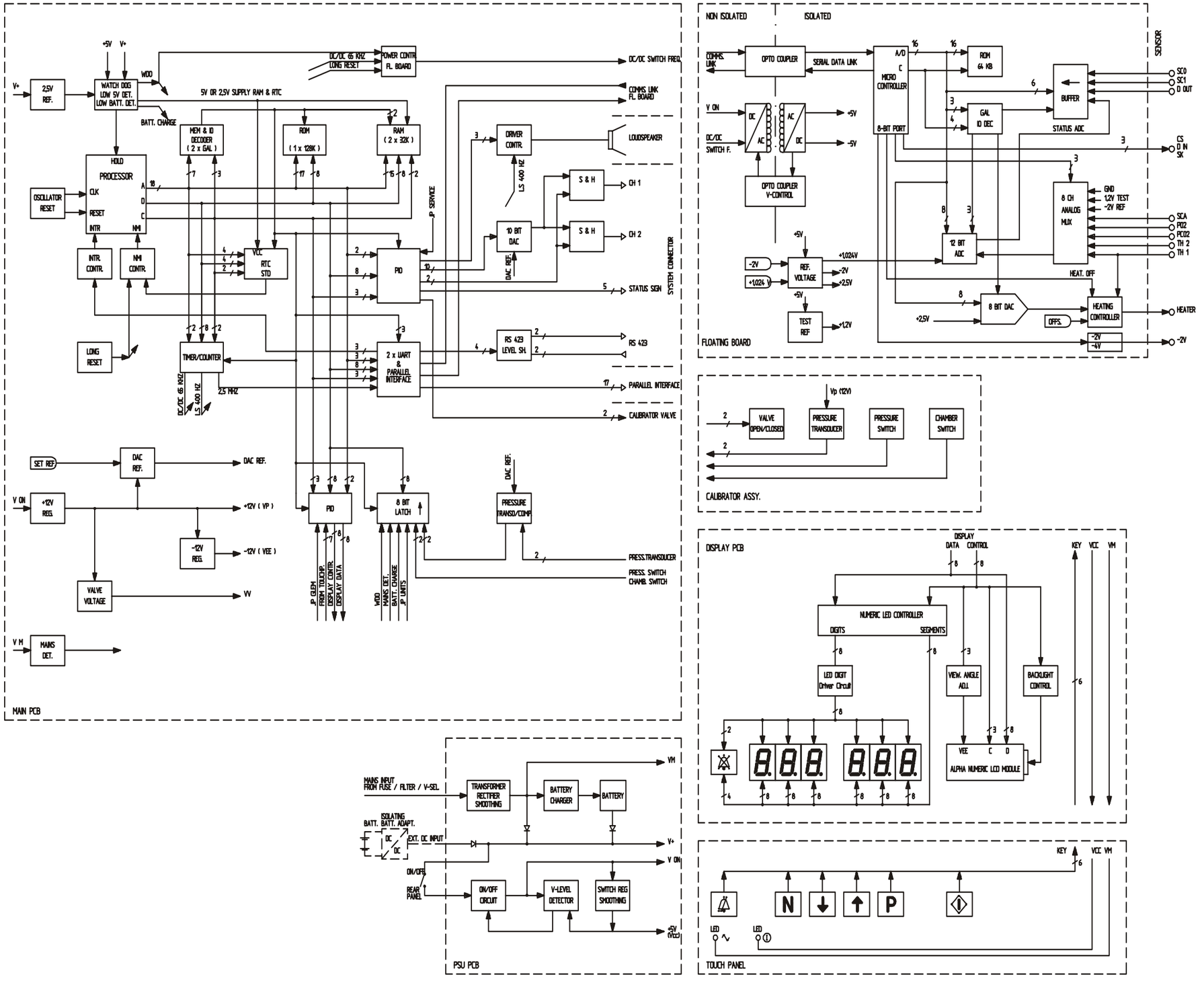
Whenever an ESI is received, the following action should be taken.

- Update the Equipment Modification record below.
- Insert the ESI in this section.

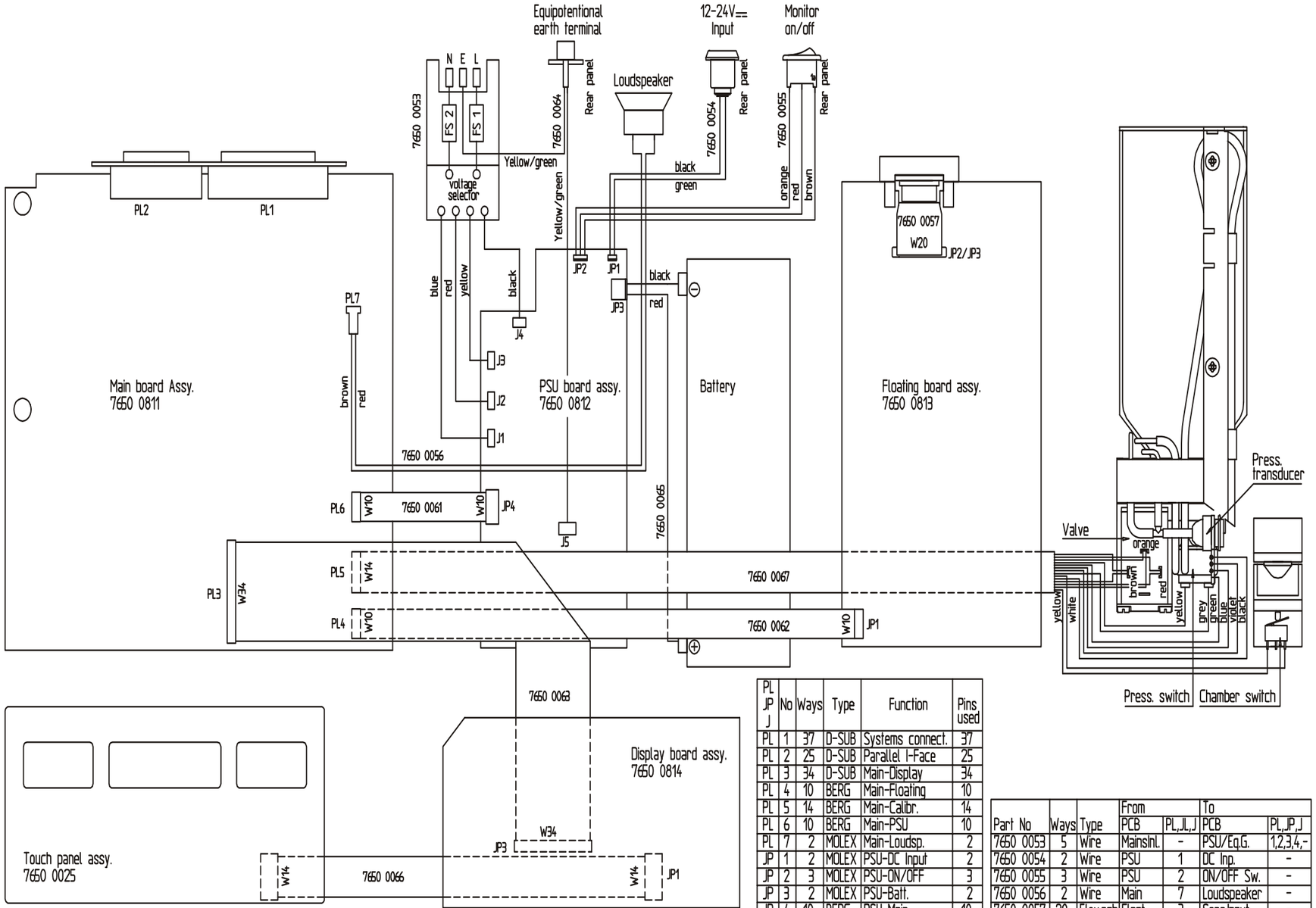
ESI Ref. No.	Issue Date	Description

9 Circuit Diagrams

9.1 Block Diagram 7650 0009 Iss. 1



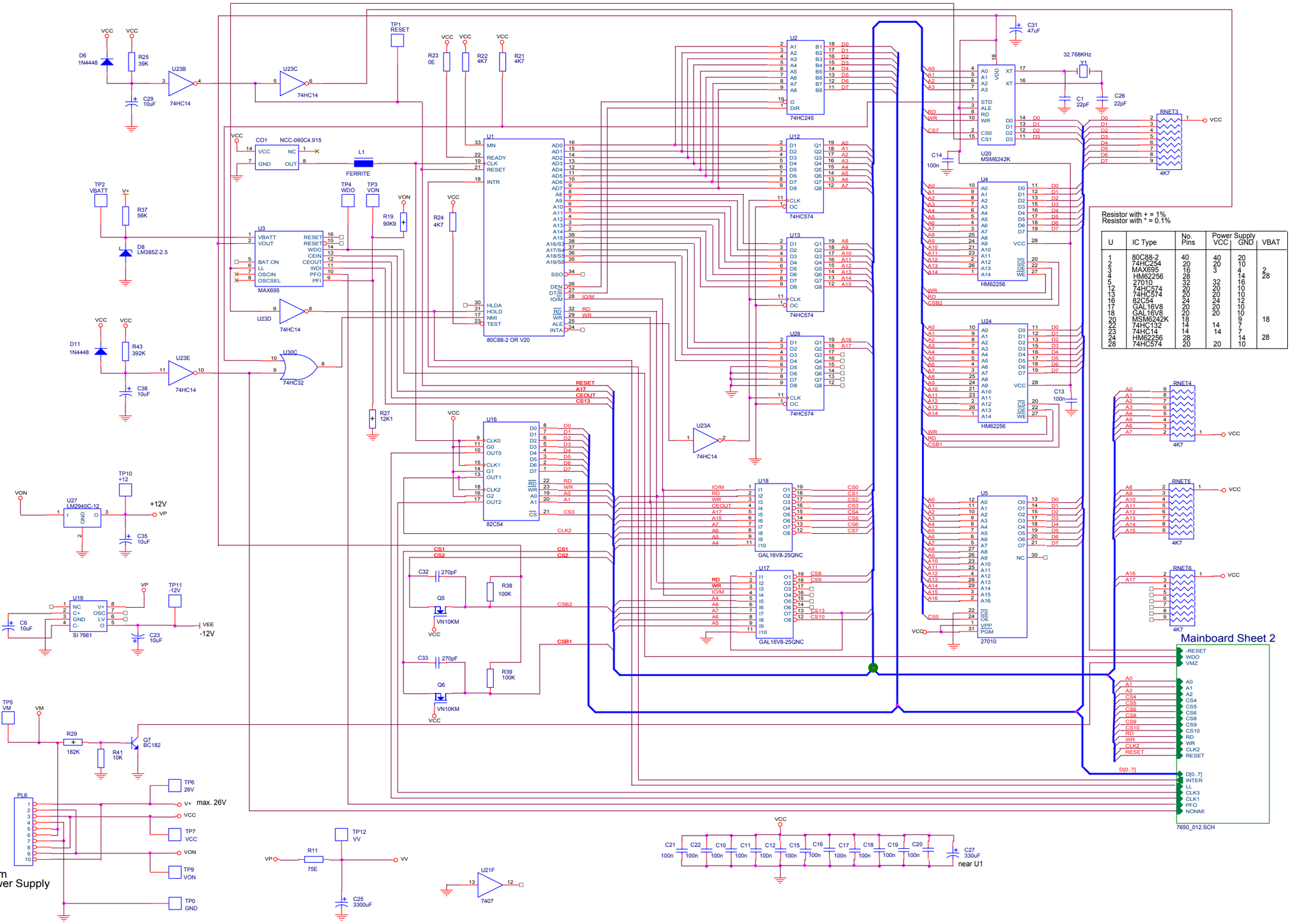
9.2 Interconnection Diagram 7650 0010 Iss. 1



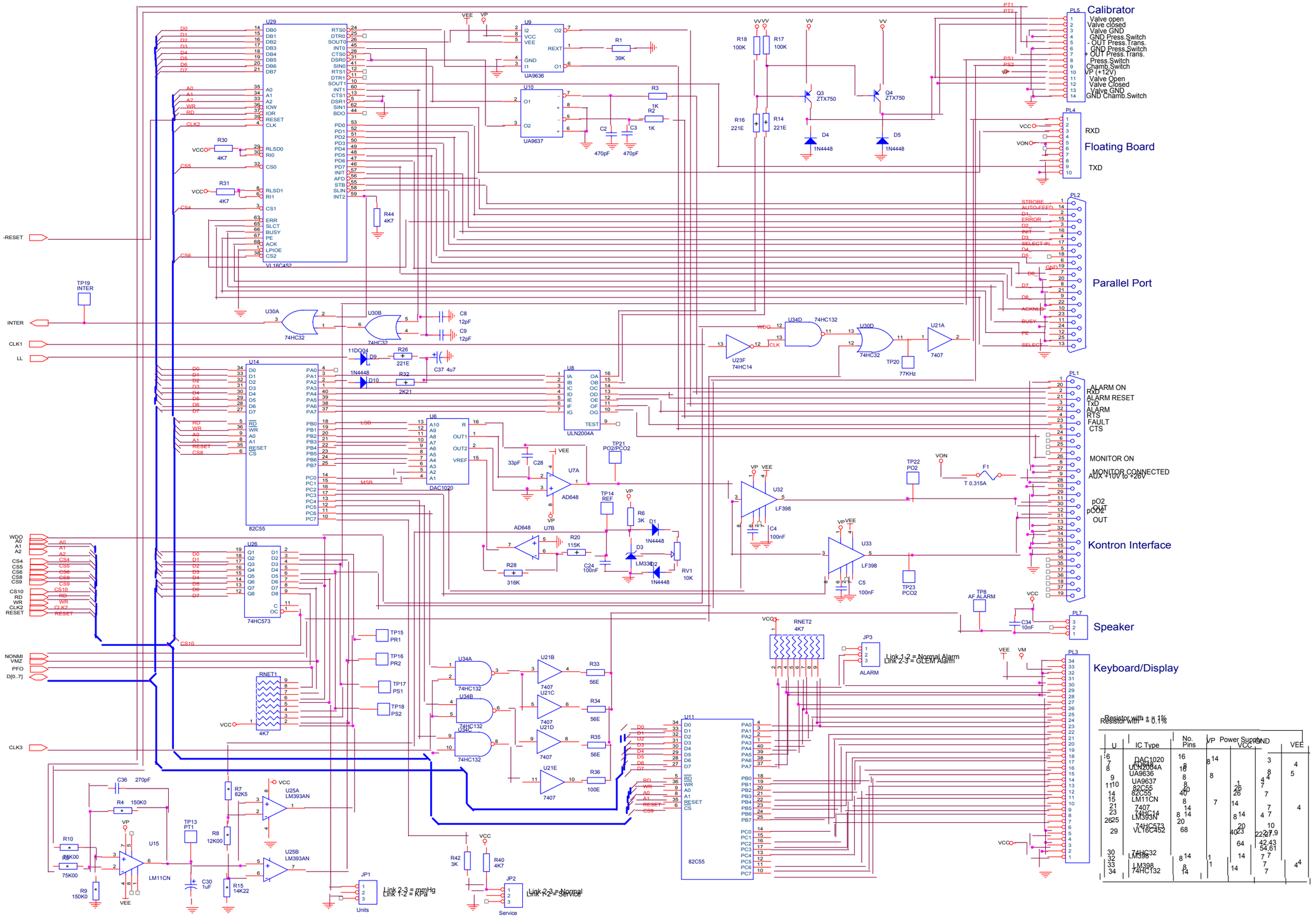
PL JP J	No	Ways	Type	Function	Pins used
PL	1	37	D-SUB	Systems connect.	37
PL	2	25	D-SUB	Parallel I-Face	25
PL	3	34	D-SUB	Main-Display	34
PL	4	10	BERG	Main-Floating	10
PL	5	14	BERG	Main-Calibr.	14
PL	6	10	BERG	Main-PSU	10
PL	7	2	MOLEX	Main-Loudsp.	2
JP	1	2	MOLEX	PSU-DC Input	2
JP	2	3	MOLEX	PSU-ON/OFF	3
JP	3	2	MOLEX	PSU-Batt.	2
JP	4	10	BERG	PSU-Main	10
J	1	1	AMP	PSU-Mains Input	1
J	2	1	AMP	PSU-Mains Input	1
J	3	1	AMP	PSU-Mains Input	1
J	4	1	AMP	PSU-Mains Input	1
J	5	1	AMP	PSU-Eq: GND	1
JP	1	10	BERG	Float.-Main	10
JP	2	20	BERG	Float.-Sens. Inp.	0
JP	3	20	FPC	Float.-Sens. Inp.	20
JP	1	14	DIL	Display-Touch pa.	14
JP	3	34	BERG	Display-Main	34

Part No	Ways	Type	From PCB	From PL,JL,J	To PCB	To PL,JP,J
7650 0053	5	Wire	Mainsinl.	-	PSU/Eq.G.	1,2,3,4,-
7650 0054	2	Wire	PSU	1	DC Inp.	-
7650 0055	3	Wire	PSU	2	ON/OFF Sw.	-
7650 0056	2	Wire	Main	7	Loudspeaker	-
7650 0057	20	Flex.pcb	Float.	3	Sens.Input	-
7650 0061	10	Ribbon	Main	6	PSU	4
7650 0062	10	Ribbon	Main	4	Floating	1
7650 0063	34	Ribbon	Main	3	Display	3
7650 0064	1	Wire	PSU	5	Eq.GND	-
7650 0065	2	Wire	PSU	3	Batterie	-
7650 0066	14	Ribbon	Displ.	1	Touchpanel	-
7650 0067	6	Ribbon separated colour	Main	5	Valve	-
"	2		"	5	Press.Switch	-
"	4		"	5	Press.trans.	-
"	2		"	5	Chamb.Switch	-

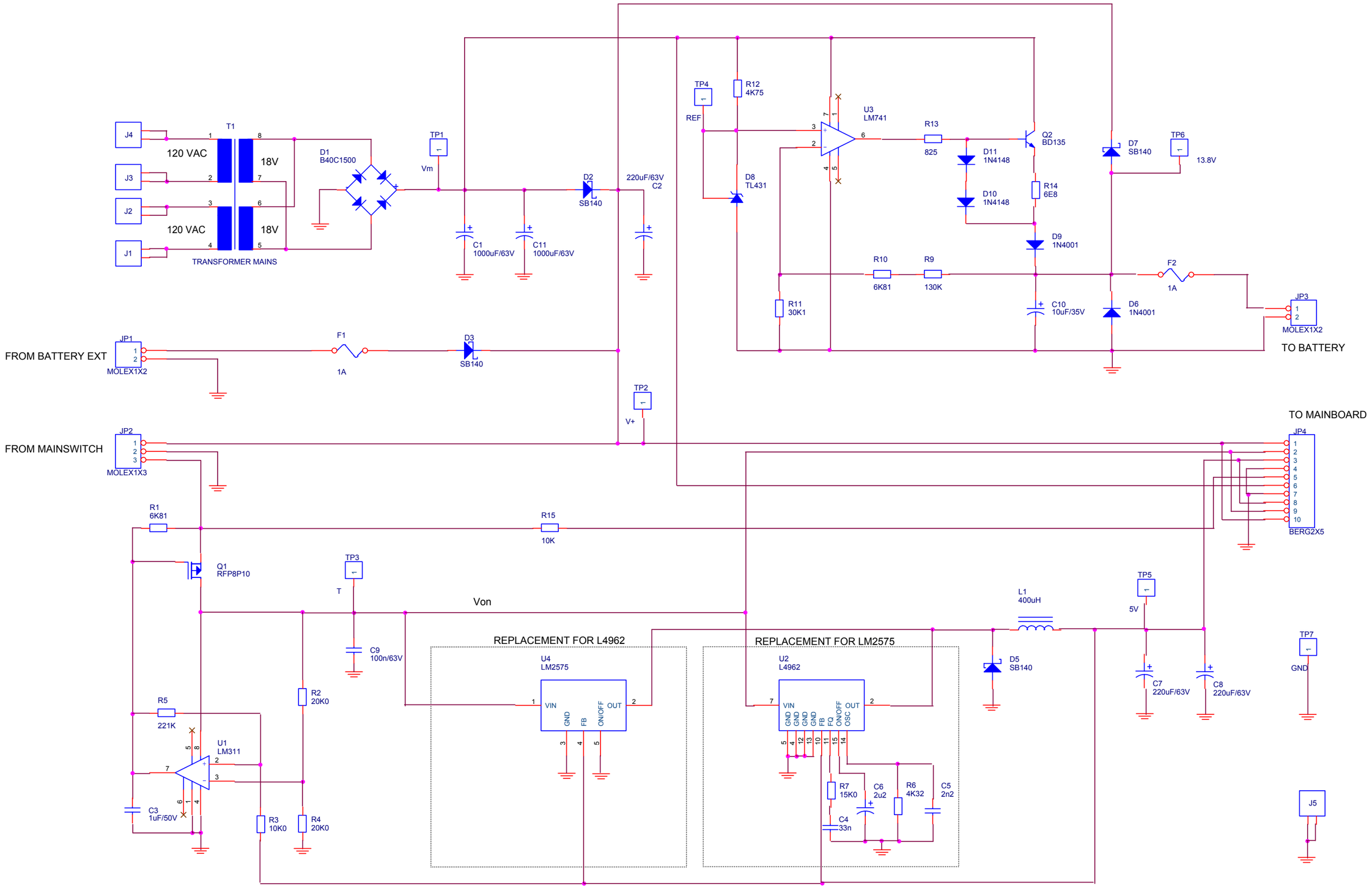
9.3 Circuit Diagram of Main PCB 7650 0821 Iss. 9 - sheet 1/2



9.4 Circuit Diagram of Main PCB 7650 0821 Iss. 9 - sheet 2/2



9.5 Circuit Diagram of Power Supply PCB 7650 0822 Iss. 7



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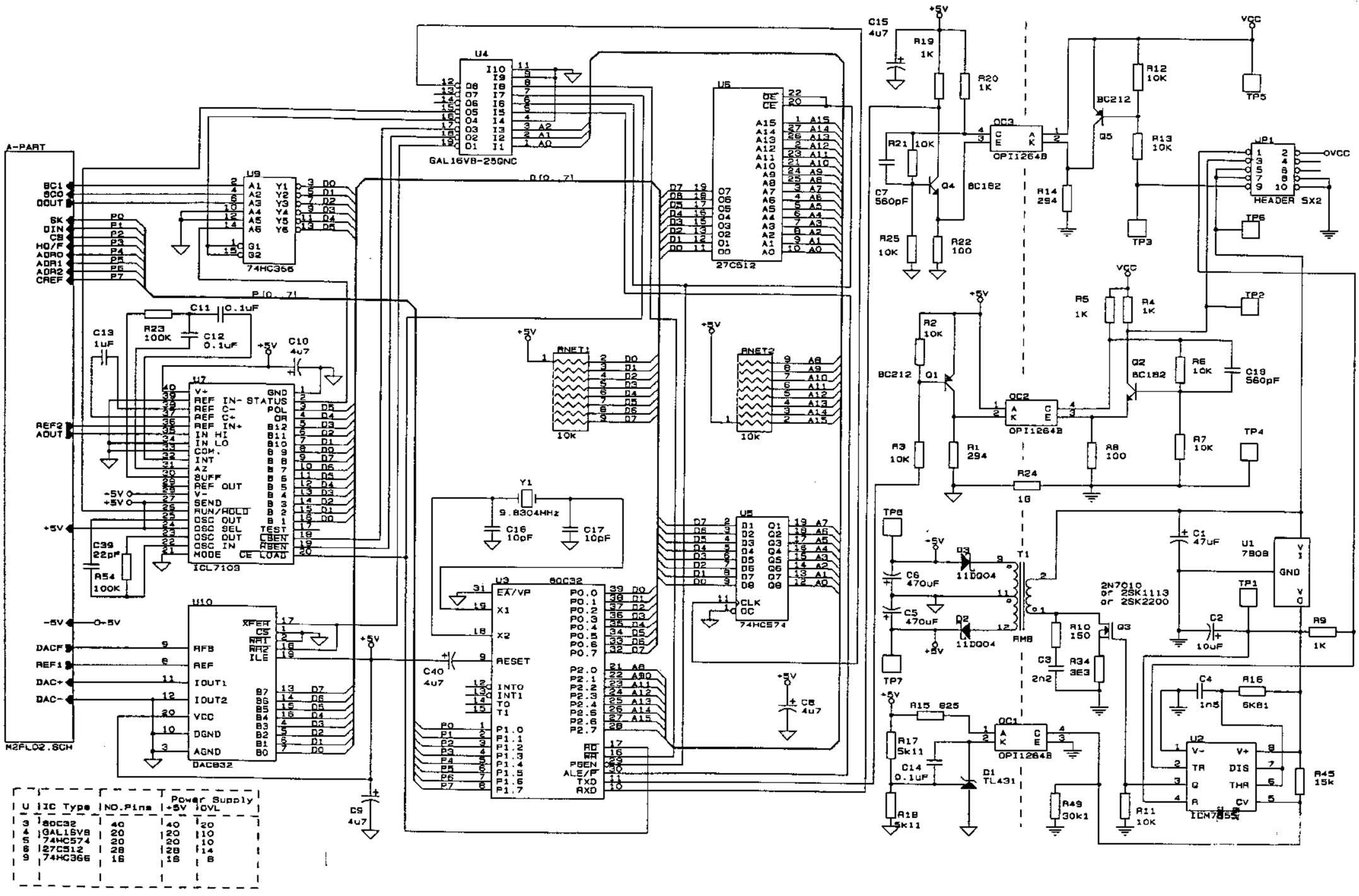
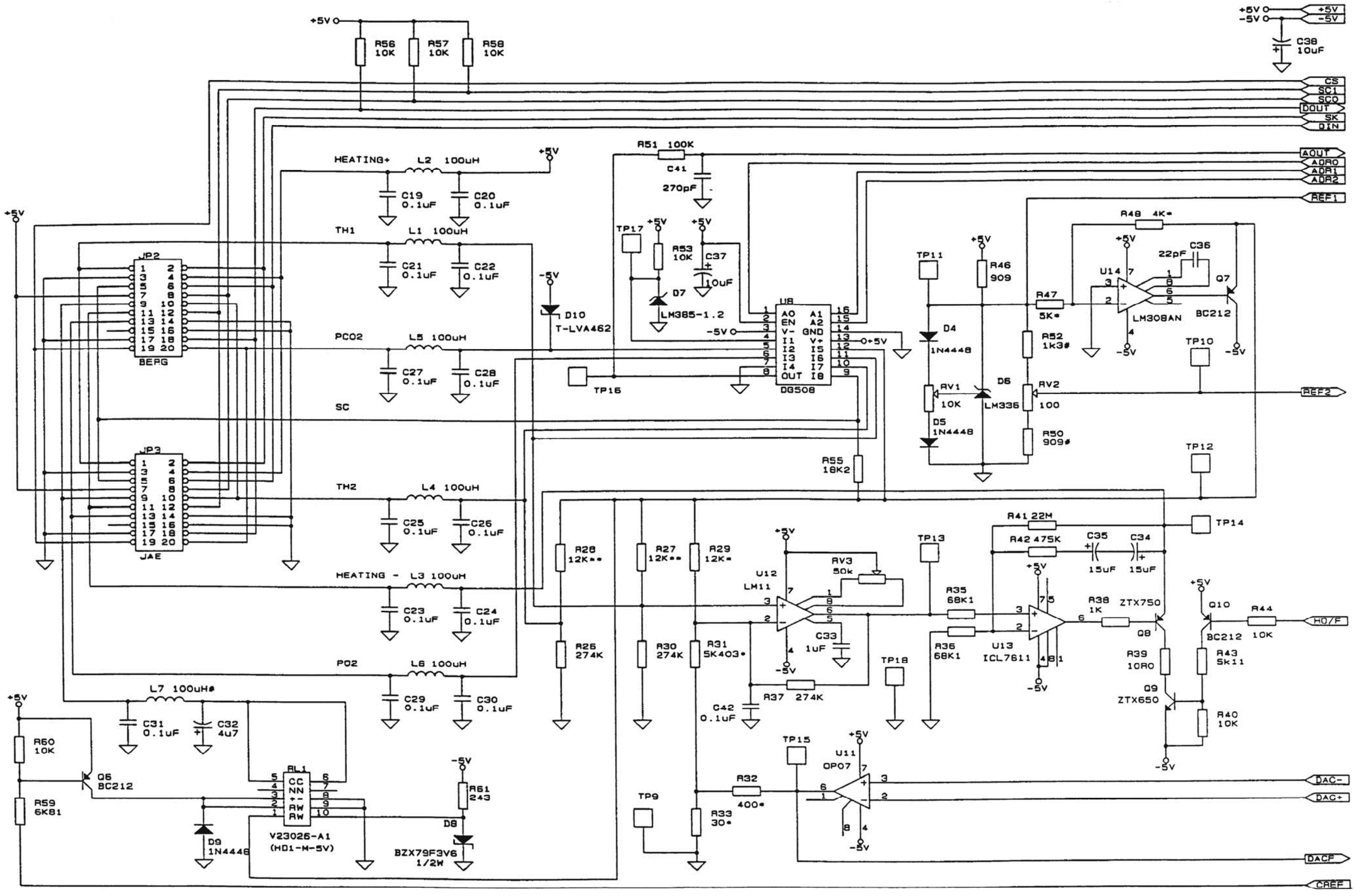
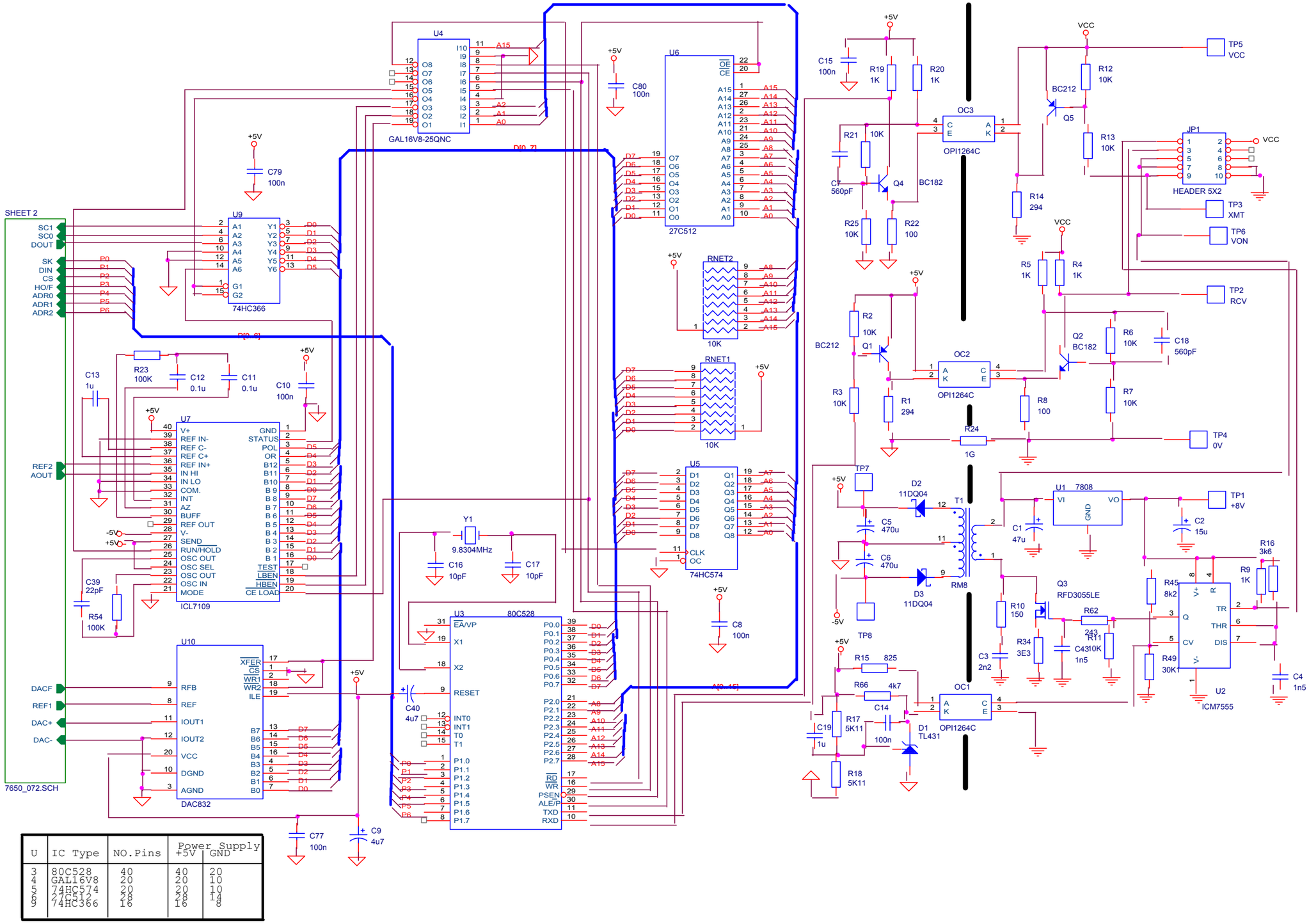
9.6 Circuit Diagram of Floating PCB 7650 0823 Iss. 7 - sheet 1/2



9.7 Circuit Diagram of Floating PCB 7650 0823 Iss. 7 - sheet 2/2

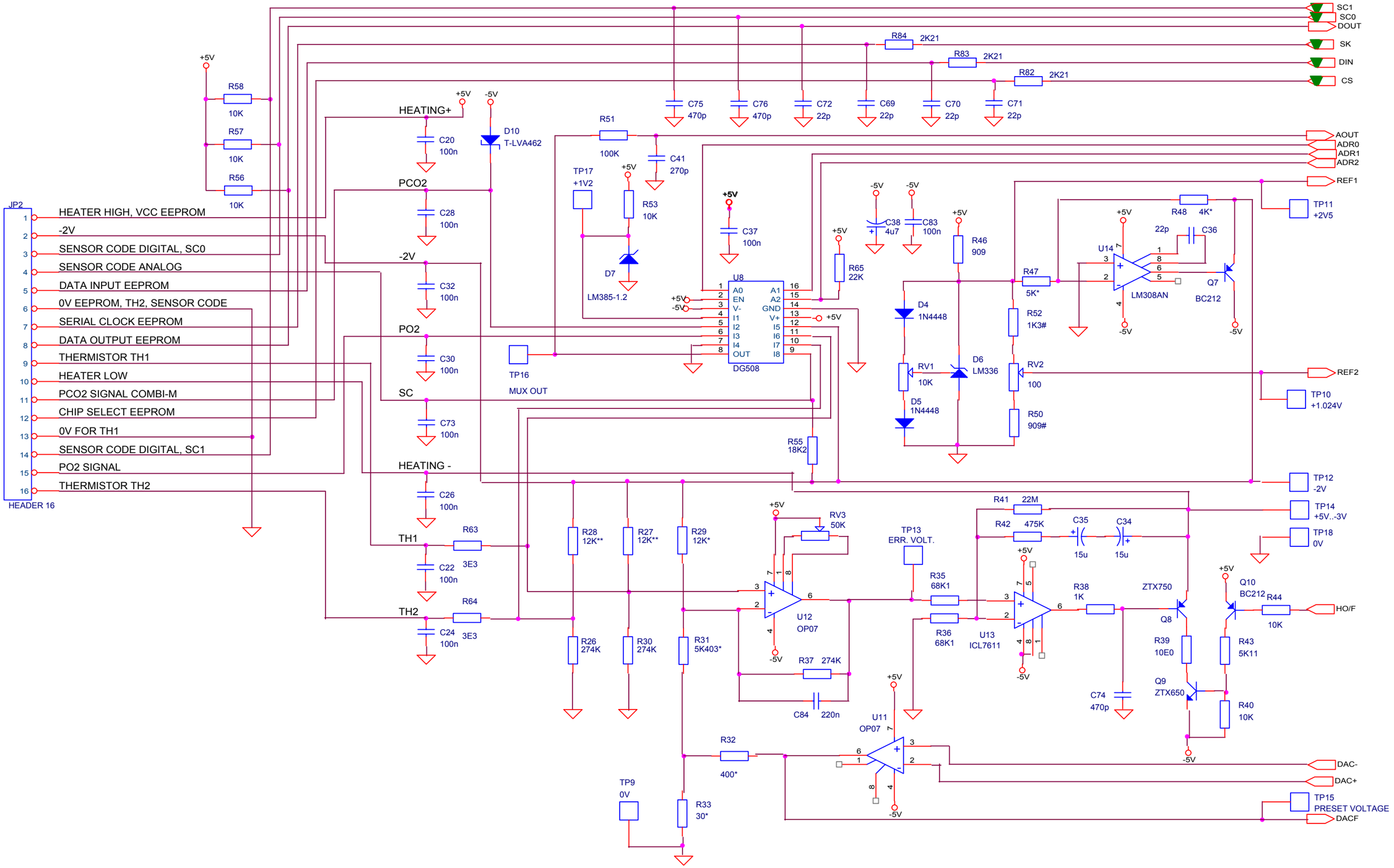


9.8 Circuit Diagram of Floating PCB (new version) 7650 0827 Iss. 4 - sheet 1/2

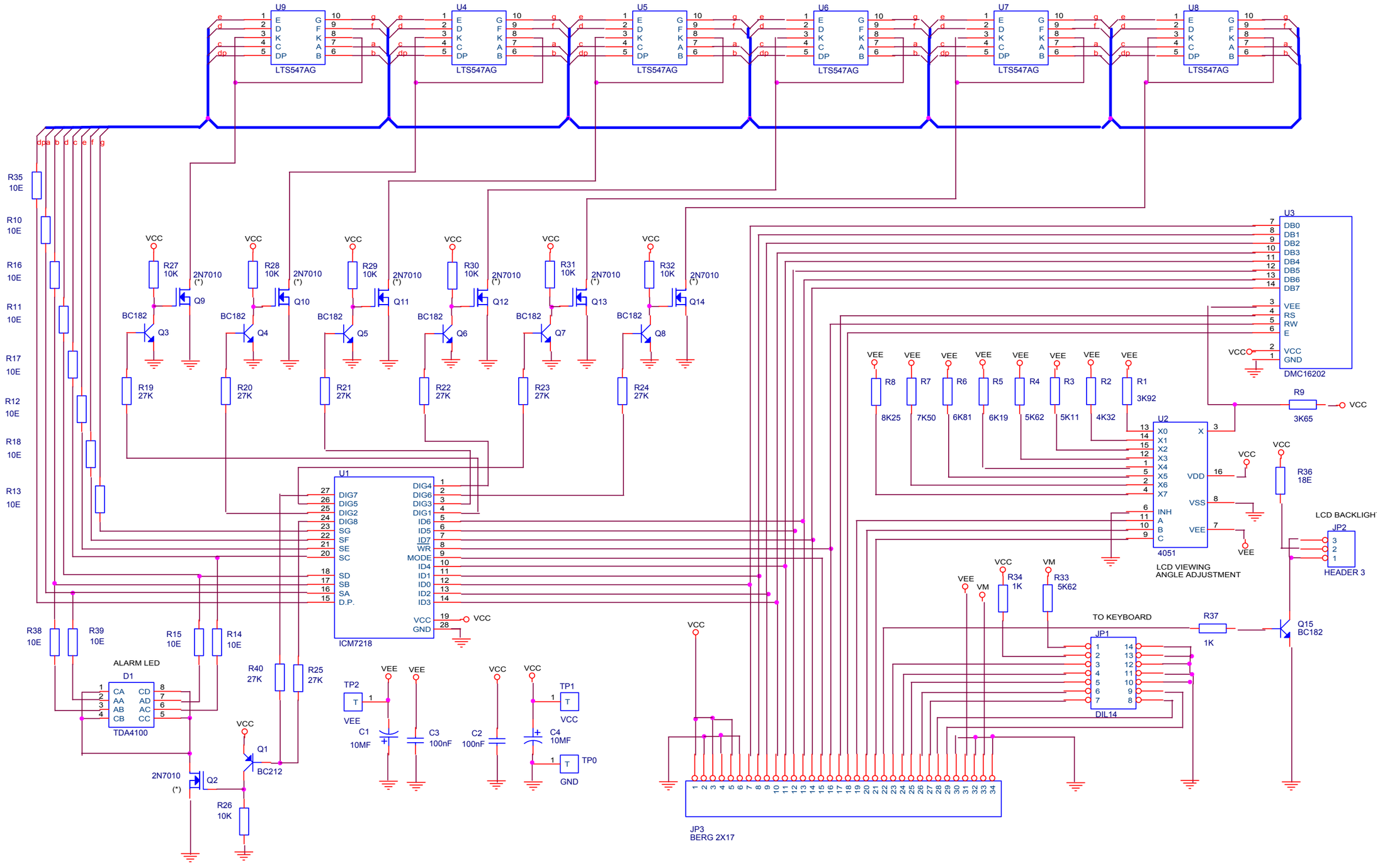


U	IC Type	NO.Pins	Power Supply +5V	GND
3	80C528	40	40	20
4	GAL16V8	20	20	10
5	74HC574	20	20	10
6	27C512	28	28	14
9	74HC366	16	16	8

9.9 Circuit Diagram of Floating PCB (new version) 7650 0827 Iss. 4 - sheet 2/2

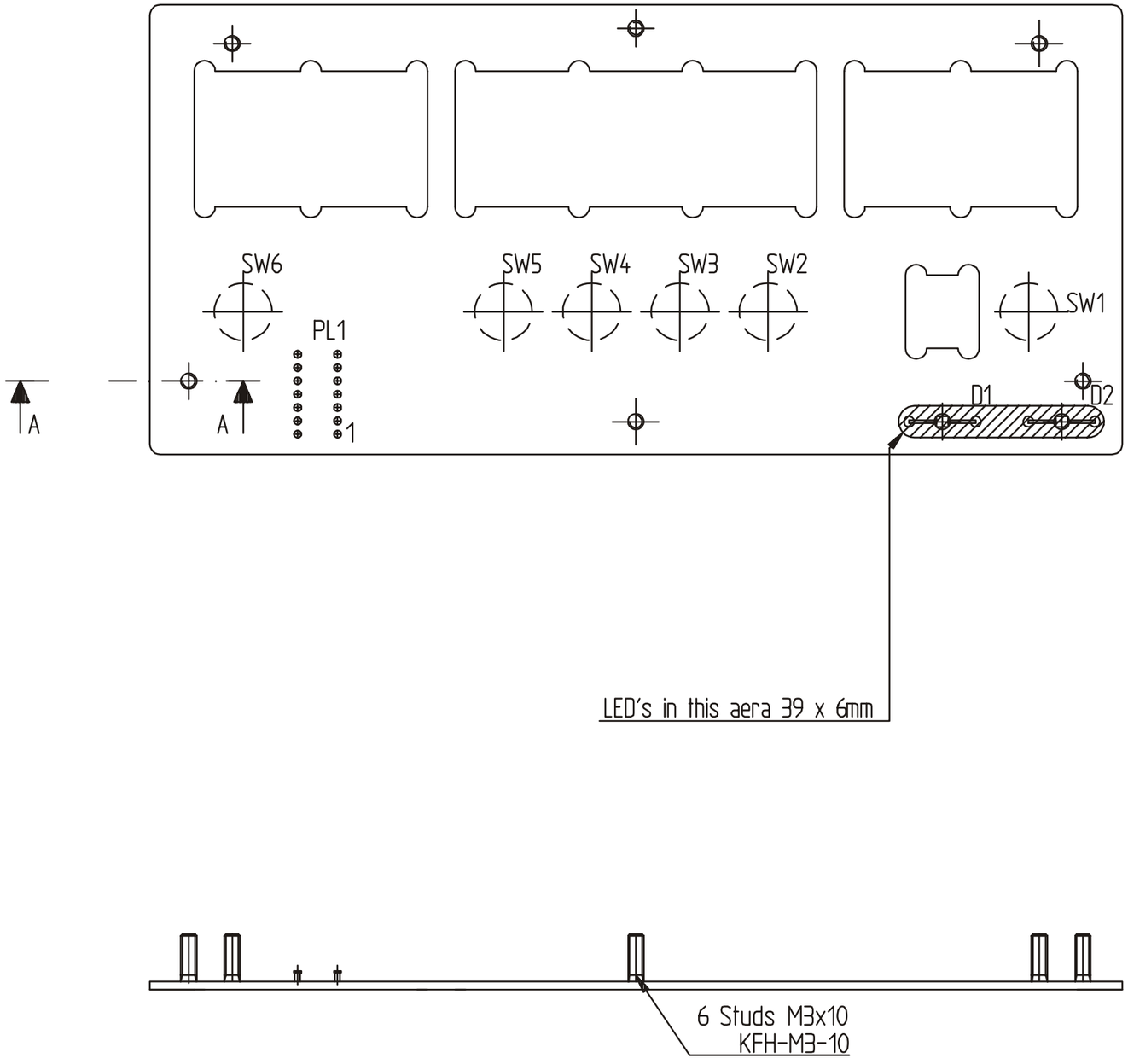


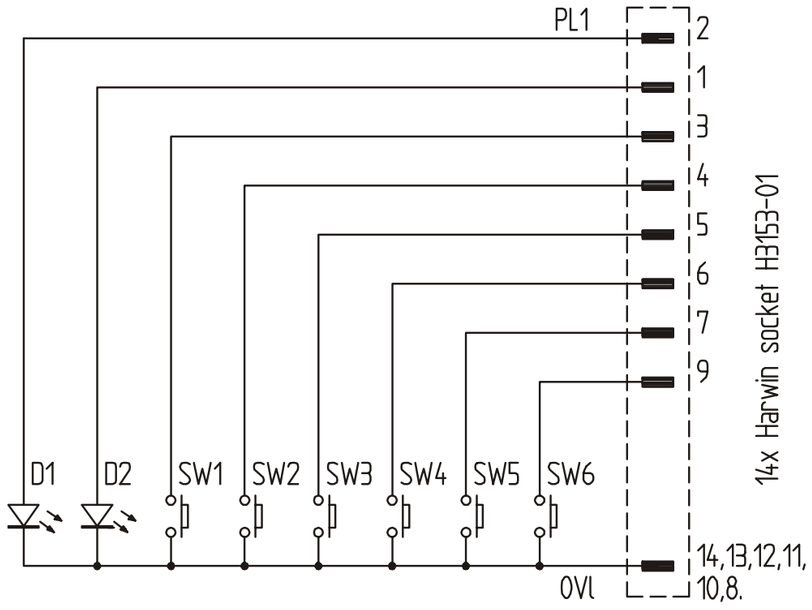
9.10 Circuit Diagram of Display PCB 7650 0824 Iss. 5



(*) = 2N7010 or 2SK1113 or 2SK2200

9.11 Touchpanel PCB 7650 0125 Iss. 5





D2:(~) Line LED yellow sub non rad lead HLMP 6400 or 6420
D1:(⏻) On-Off LED green sub non rad lead HLMP 6500 or 6520
SW1-SW6: Snap domes

10 Packing for Shipment

10.1 Introduction

To ship the monitor for any reason, follow the instructions in this section.

Returning the MicroGas 7650

Contact Linde Medical Sensors Technical Service or your local Linde Medical Sensors representative for shipping instructions. Unless otherwise instructed by Linde Medical Sensors Technical Services, it is not necessary to return the sensor or other accessory items with the monitor. Pack the MicroGas 7650 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the monitor during shipping.

Return the MicroGas by any shipping method that provides proof of delivery.

General instructions

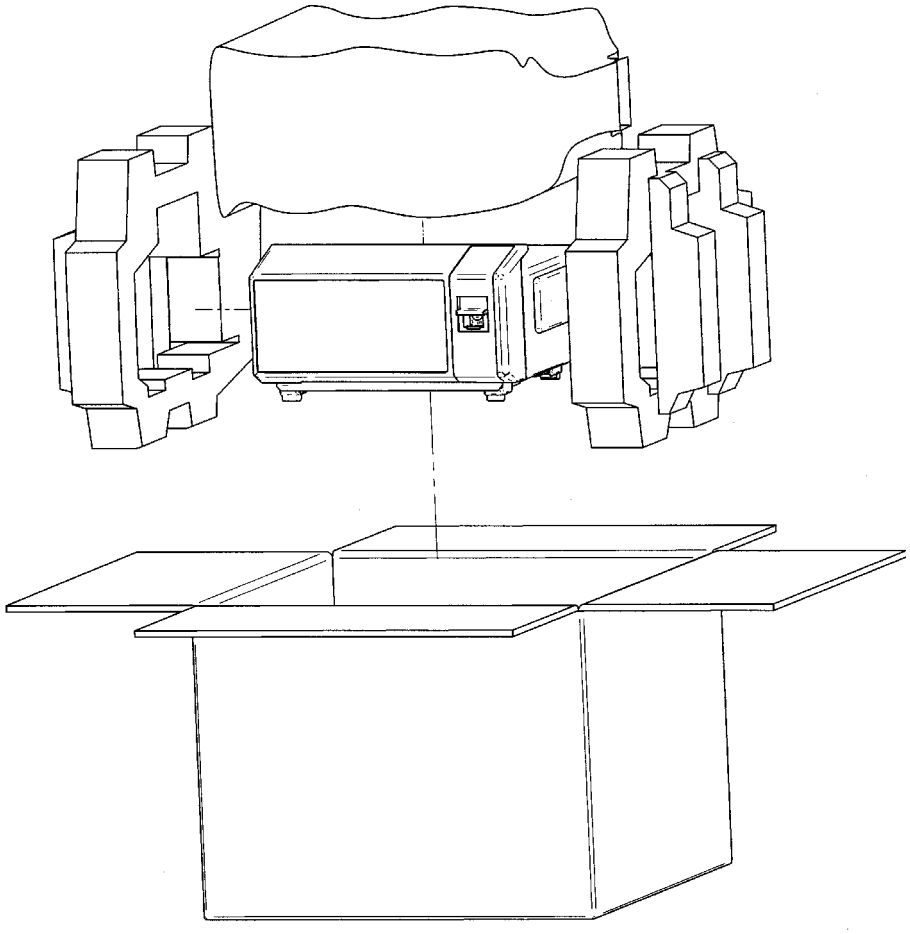
Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Linde Medical Sensors warranty. If the original shipping carton is not available, use another suitable carton.

10.2 Repacking in Original Carton

If available, use the original carton and packing materials. See Figure below.

Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.



2. Place in shipping carton and seal carton with packaging tape.
3. Label carton with shipping address and return address

10.3 Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the MicroGas 7650:

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with a bursting strength of at least 1500 kPa.
3. Fill the bottom of the carton with at least 10 cm of packaging material.
4. Place the bagged unit on the layer of packaging material and fill the box completely with packaging material.
5. Seal the carton with packaging tape.
6. Label the carton with the shipping address and return address.

11 Reporting Procedures

11.1 Handling and Reporting of Incidents

1. Purpose
   To ensure that the processes for monitoring adverse incidents, managing the related corrective actions and reporting to the competent authorities are done in a controlled way and in accordance with the legal requirements.

2. Scope
   All products of Linde Medical Sensors (formerly “Kontron Instruments Medical Sensors”)

3. Definitions
   - Adverse Incident (CD 93/42/EEC, Art. 10.1a.): Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to (=“near“ incident) or might have led to the death of a patient or a user or to a serious deterioration in his state of health. An Adverse Incident is equivalent to a “MDR Reportable Event” as defined in 21 CFR, Ch. 1 , §803.3(q) and to an “ incident that meets the Mandatory Problem Reporting” as defined in the Canadian MDR, Section 59(1).
   - Recall (EN 46001, 3.15): When there is a risk of death or serious deterioration to the state of health, recall is:
     - the return of a medical device to the supplier,
     - its modification by the supplier at the site of installation,
     - its exchange or its destruction

     in accordance with the instructions contained in an advisory notice.
     A recall as defined above is equivalent to “Corrections and Removals” as defined in 21CFR Ch.1 §806 in the USA.
     The canadian definition of a recall according to the section 1 of Medical device Regulation is different. A recall in Canada includes any action taken by the manufacturer not only after becoming aware that the device may be hazarous to health, but also when it may fail to conform with any claim made by the manufacturer relating to its effectiveness, benefits, performance characteristics or safety or when it may not meet the requirements of the act or the CMDR.
   - Advisory Notice (EN 46001, 3.14): A notice issued to provide information and/or advise on what action should be taken in the use, modification, disposal or return of a medical device.
   - Competent Authority: Appointed state authority to operate the medical device vigilance system on the market in accordance with legal requirements.
   - Notified Body: Appointed body acknowledged by the EU to both approve for CE marking any medical devices after assessing its compliance with the requirements of the MDD and to operate surveillance audits. The Notified Body competent for LIMS is TÜV Product Service in Munich, Germany.
   - Designated Agent in the USA: According to 21 CFR Ch.1, §407.40, LIMS has to handle all matters concerning the US Medical Device Reporting regulations via its designated agent in the USA
   - Importer of a Medical Device: According to the Canadian MDR, Section 59 to 62, LIMS will handle all matters concerning the “Mandatory Problem Reporting” and a “Recall” via its designated agent in Canada.

4. Monitoring and identification of adverse incidents
   Any LIMS employee shall immediately inform the SBKR, when he receives or otherwise becomes aware of information from any source, that reasonably suggests that a device marketed by LIMS may have caused or contributed to a death or serious injury, or has malfunctioned and such device or similar device marketed by LIMS would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
   The SBKR shall constantly monitor complaints and all product information available in the quality assurance system of LIMS, to identify potential adverse incidents.
   All distributors of LIMS products have committed themselves to notify LIMS immediately of any adverse incident or near adverse incident. According to the Medical Device Reporting regulations (21 CFR Ch. 1 , §804.25), the Designated Agent in the USA must submit to LIMS a report not later than 10 working days after he receives or becomes aware of information about an adverse incident.
   When such incident is suspected, then the following will apply: The SBKR shall immediately call a Review Committee made up of Managing Director, R&D Manager, Marketing Manager, QA Manager, SBRA and SBKR to assess if it is or not the case of an adverse incident. (according to the Form F187) The result of their assessment shall be documented in a report. This report must contain any information evaluated by the Review Committee. If the result of their assessment is negative (adverse incident not confirmed), the reasons for this decision must be documented. The report has to be added to the Adverse Incident File (see chapter 10) also when an adverse incident has not been confirmed.
   If the result of their assessment is positive, the SBRA shall inform the Notified Body in the EU (TÜV Product Service) and, when products delivered to the USA or Canada are affected as well, the Designated Agent in these countries. If remedial actions should be required to prevent an unreasonable risk of substantial harm to the public health, the SBRA shall alert the Designated Agent in the USA, indicating that a Five-day Report according to 21 CFR, Ch. 1 , §803.53, has to be submitted to FDA.
   Immediately thereafter, the SBKR shall prepare a corrective action plan which must be submitted to the Review Committee within two working days.

5. Preparation of corrective action plan
   - The SBKR shall
     - identify quantity and location (country) of the products concerned that have been delivered, by serial number or lot number.
     - identify reasons for the problem behind the incident by coordinating a Product Failure Investigation according to QS-RL 053.
     - provide, together with R&D, recommendations for a MFA notice, including technical reasons and consideration of patient and user risks.
   - The SBRA shall
     - prepare drafts of initial adverse incident reports to the Competent Authorities of those countries where the incident has happened or might happen. The reports should include a statement to the effect that the report is made without prejudice and does not imply any admission of liability for the incident or ist consequences.

6. Corrective action plan
   The Review Committee shall decide within additional two working days on the corrective actions which have to be taken and their timing. The following checklist must be considered for guidance.
   - Stop shipment of products affected.
   - Drafts of adverse incident reports to the competent authorities
   - Recall of products affected via a MFA notice
   - Draft of a “Corrections and Removals Report” to the US FDA (see QS-RL 068, chapter 4.1)
   - Letter to distributors
   - Letter to customers (to be mailed via distributors)
   - Review of all written documents by a lawyer

   The corrective action plan should be established in relationship to the seriousness of the problem, the quantity of already delivered products and the technical solutions available. A copy of the corrective action plan will be added to the Adverse Incident File (see chapter 10).

7. Implementation of corrective action plan
   - Stop shipment of products affected: This shall be implemented immediately according to QS-RL 055.
   - Letter to distributors: Following the decisions taken by the Review Commitee, the LIMS Managing Director (GL) shall issue immediately a letter to the Managing Directors of the distributors of the countries affected with following contents:
     - Products affected (with serial numbers or lot numbers)
     - Description of the identified problem (reported incident or potential incident or fault)
     - Consequences of the problem on patients or operators (and materials or other equipments, if applicable).
     - Advice on stop shipment from distributors.
     - Advice on short term checks or by-pass solutions or any possible precautions to be taken for installed bases.
     - Information on MFA notice to be issued shortly and on type of intended recall.
     - A sample letter to users advising of any potential risk and short term precautions to take.
     - Instructions to distributors about whether the letter to users must or may be issued.
   - Recall of products affected via a MFA notice: This shall be implemented according to QS-RL 068 within the timescale specified in the MFA.
   - "Corrections and Removals Report" to the US FDA: This shall be implemented according to QS-RL 068.

8. Reporting of Incidents
   Adverse Incidents must be reported to the Competent Authority of the country where the incident has occurred. In addition, the Competent Authorities of those countries must receive a report, where the same or a similar type of device produced by LIMS is in use and would be likely to cause or contribute to a death or a serious injury, if the malfunction were to recur.
   LIMS will submit the formal reports to the Competent Authorities in the EU and to the Designated Agent in the USA (21 CFR Ch. 1 , §803.58) and Canada. For the USA and Canada, SBRA will prepare draft reports which contain all information (as available) required for the formal reports. The SBRA will forward the reports to their Designated Agent in the USA and in Canada as expeditiously as possible and early enough to allow them to submit the formal reports within the time limits given below. The time runs from LIMS being first informed of the incident, to the relevant Competent Authority receiving the notice.

   The procedures and time limits for submitting the reports are as follows:
   - Switzerland: The report must be prepared according to the Swiss MepV (Information at INFO_VIG. doc) and has to be sent directly to the Swiss Federal Office of Public Health within 10 days for incidents and 30 days for near incidents.
   - Member States of the EEA (European Economic Area): The report must be prepared according to the guideline MEDDEV 2.12/1 and has to be sent to the Competent Authorities of all member states concerned. Incidents must be reported within 10 days, near incidents within 30 days.
   - Countries outside the EEA, except the USA and Canada: The report must be prepared according to the guideline MEDDEV 2.12/1 and has to be sent to the Competent Authority of Germany (Bundesinstitut für Arzneimittel und Medizinprodukte). This is requested as the Notified Body of LIMS is located in Germany. Incidents must be reported within 10 days, near incidents within 30 days.
   - USA: The report must be prepared according to 21 CFR Ch.1, §803, Subpart E by the Designated Agent of LIMS in the USA. LIMS has to provide all relevant information to the Designated Agent, who has to submit the report to the FDA within 30 days. If the special conditions according to §803.53 apply, the report has to be submitted within five days.
   - Canada: The reporting shall be done according to the sections 59 to 62 of the Canadian MDR and the guidance "Mandatory and Voluntary Problem reporting for Medical devices".
     A preliminary report must be prepared according to the section 60 (2) of the CMDR and shall be sent o the competent authorities within 10 days for incidents and 30 days for near incidents. For incidents that occurs outside Canada, as soon as possible after indication of intention to take corrective actions (see CMDR Section 60 (1)(b)).
     A final report according to the section 61 of the CMDR shall be submitted within the time established in the preliminary report.
     According to section 62 of the CMDR, a summary report can be requested by the competent authorities and shall be submitted within 30 days of the request.

9. Follow-up of corrective action plan
   - Recall of products: The progress of the recall and its completeness is monitored by the SBKR as outlined in QSRL 068.
   - Supplemental reports to the Competent Authorities: The SBRA is responsible for issuing supplemental reports and the final report to the Competent Authorities according to the guidelines and regulations mentioned above. This shall be done in coordination with the Designated Agent in the USA, if applicable.

10. Retention of documents
    The SBKR is responsible for establishing and maintaining an Adverse Incident File (US term: "MDR Event File") which is a part of the Complaint File (see QS-RL 020). The Adverse Incident File must contain all documents of the regular Complaint File and, in addition, the following:
    - Assessment report of Review Committee (see chapter 4)
    - Corrective action plan (see chapter 6)
    - Copies of all reports to the Competent Authorities
    - All information supplied to distributors, customers and related documentation
    - Copies of correspondence related to the Adverse Incident
    - The product failure investigation report (see QS-RL 053) shall contain the aditional information required by 21 CFR Ch. 1 , §820.198d.

    The Adverse Incident File must be retained as a quality record for 13 years following the termination of the supply of the relevant product.

11. Associated Documents
    QS-Richtlinien Nr.:

100.93.017	Korrektur- und Vorbeugungsmassnahmen (Kap. 14)
100.93.020	Rückmeldung von Kunden (Kap. 14)
100.93.053	Produktfehler – Untersuchung (Kap. 4)
100.93.055	Lieferungsstopp (Kap. 14)
100.93.068	Management of MFA, ESI and TB (Kap. 14)
100.93.010	Qualitätssystem-Aufzeichnungen (Kap. 16)

    Form:

F187	Entscheidungskriterien zur Meldepflicht bei einem Vorfall mit einem medizinischen Gerät

11.2 Management of MFA, ESI, TB

1. Purpose
   To define the rules for the preparation and management of information and actions relating to Mandatory Field Actions (MFA), Engineering Service Information (ESI) and Technical Bulletins (TB).

2. Scope
   All products of Linde Medical Sensors (formerly Kontron Instruments Medical Sensors). For MFAs, this procedure is linked to the Procedure on Handling and Reporting of Incidents (QS-RL 070) and cannot be operated without it.

3. Definitions

   MFA:
   Mandatory Field Action notice: An advisory notice which has the purpose to instruct distributors to carry out prescribed remedial actions in order to avoid potential risks either to the patient or user within a specified period, in any case not to exceed one month after receipt. An MFA is issued in the case of a recall following an adverse incident (see QS-RL 070). The MFA requires that distributors confirm that the prescribed actions have been taken.

ESI:
Engineering Service Information: This advisory notice is intended to supply information revealing a serious failure in expected performance, where patient or user safety is not jeopardised, and to suggest corrective action. As with the MFA, the provision of an ESI indicates an obligation to undertake the necessary actions on the products concerned, as defined by their serial numbers or lot numbers.
The obligation to undertake such repairs, placed on the distributor, take the following two forms as defined in the first page of the ESI document (Annex C):

ESI Code 1 Mandatory for completion within a maximum of six months on all products concerned.
ESI Code 2 Should be carried out on all products concerned at the time of next repair, next preventive maintenance, visit or after a customer complaint.

TB:
Technical Bulletin: The Technical Bulletin (TB) is an advisory notice designed to provide information concerning the optimization of performance or expected useful life of the product, for example:
- Means of improving the product's performance
- New options and features for an existing product
- Software evolution
- Service policy

The issue of a TB typically happens following a design change, bug fix, product improvement, upgrade or evolution, customer complaint.
Unlike the MFA and ESI, the issue of a Technical Bulletin does not necessarily require any action by the distributor who receives it. No follow-up is required from SBKR.

SBKR:
is a technical support function at LIMS responsible for installed base serviceability, user satisfaction and after-sales service, acting as interface with relevant engineering and manufacturing functions.

SBRA:
is the person responsible for regulatory affairs who is in contact with the notified body, the competent authorities in the EU, in the USA, Canada and other countries via our local distributor/agent..

4. Implementation

4.1 Mandatory Field Action (MFA)

SBKR:
Must prepare the MFA in the english language using the form and the contents described in Annex B.

Must use accredited design and production documents. Documents drawn up on the purpose (such as diagrams) may also be attached to the MFA, if necessary.

If applicable, the parts list (kit specification) must always be attached to the MFA.

The validation section of the document (Annex B) must be signed at the foot of the first page by the designated persons (Managing Director and SBRA) before being issued. Whilst pending, the document should be marked "provisional".

Must prepare a list specific to each distributor identifying the serial number of each product or the lot numbers affected and include this information in the MFA delivered to the distributors (see Annex A). This list of serial numbers or lot numbers is drawn up using factory records. Where the product affected does not have serial or lot numbers (i.e. an accessory or component), then the Annex A must contain information about delivery notes, delivery dates and quantities affected for each distributor.

Shall ensure that the contents of the MFA are approved by the QA Manager, the R&D Manager, the Production Manager and the Marketing Manager.
Optional requirement: the form F178 may be used to provide documented evidence of the approval process.

SBRA:
Must submit copies of the MFA notice to the competent authorities in the EU according to the requirements outlined in the EC Guidelines MEDDEV 3/93 rev.3, §5.7.

Must prepare a draft of a “Corrections and Removals Report” to the US FDA. This report is required according to 21 CFR, Ch. 1 , §806, and has to be submitted to FDA by the Designated Agent in the USA (SensorMedics Corp.) within 10 working days of initiating the recall. The draft report has to contain all information (as available) required by the Designated Agent to prepare the formal report. The SBRA will forward the draft as expediously as possible and early enough to allow the Designated Agent to submit the formal report in time.

Must prepare a draft of a recall notification according to the Canadian MDR Section 64, using the Guidance for Medical devices Complaint handling and Recalls, which has to be submitted to the competent authorities in Canada by our designated agent before undertaking the recall.

Distributors / Agents:
Are responsible to submit the formal recall notification to the competent authorities if applicable and implement all the requirements of the MFA document within the specified time from receipt of the MFA and in any case within one month from such a date.
Must confirm to SBKR within the same timescale that all actions required in the MFA have been carried out by serial numbers or lot numbers using the form as per Annex A (F179).
Must submit the formal completion report to the competent authorities if applicable.

SBKR:
Is responsible to audit that all MFAs have been performed in a timely manner (by means of a document audit: all Annexes A or equivalent have been returned and are completed) and to ensure that adequate measures are taken to complete the remaining ones.

4.2 Engineering Service Information (ESI)

SBKR:
Must prepare the ESI according to the following rules:

ESI Code 1: Mandatory for completion within a maximum of six months on all products concerned.
ESI Code 2: Mandatory and to be carried out on all products concerned at the time of next repair, next preventive maintenance or after a customer complaint.

After the issue of an ESI Code 1, SBKR must carry out the following 3 actions:

1. Prepare a list specific to each distributor identifying the serial numbers or lot numbers of the products affected and include this information in the ESI delivered to the distributor (see Annex A). This list of serial or lot numbers is drawn up using factory records. Where the product affected does not have serial or lot numbers (i.e. an accessory or component), then the Annex A must contain information about delivery notes, delivery dates and quantities affected for each distributor.

2. Ensure that modifications to the products so identified must be carried out within the timescale established after receipt of the ESI and associated kits.

3. As in the case of an MFA, and using the same procedure, SBKR must receive confirmation of completion of any modifications and ensure consistent operation.

Shall ensure that for all ESI (code 1 and 2):

- The ESI is prepared in the english language using the form and the contents described in Annex C.

- Accredited design and production documents are used. Documents drawn up on the purpose (such as diagrams) may also be attached to the ESI, if necessary.

- If applicable, the parts list (kit specification) is attached to the ESI.

- The validation section of the document (Annex C) are signed at the foot of the first page by the designated persons (SBKR and EL) before being issued. Whilst pending, the document should be marked "provisional".

- The contents of the ESI are approved by the QA Manager, the R&D Manager, the Production Manager and the Marketing Manager. Optional requirements: the form F178 may be used to provide documented evidence of the approval process.

SBRA:
Must prepare a draft of a recal notification according to the Canadian MDR Section 64, using the Guidance for Medical devices Complaint handling and Recalls, which has to be submitted to the competent authorities in Canada by our designated agent before undertaking the recall.

Distributors / Agents:
Are responsible to submitt the formal recall notification to the competent authorities if applicable and implement all the requirements of the ESI code 1 document within a maximum of 6 months from receipt of the ESI and relevant kits (if necessary).
Must confirm to SBKR within the same timescale that all actions required in the ESI code1 have been carried out by serial numbers or lot numbers using the form as per Annex A (F179).
Must implement all the requirements of the ESI code 2 document on all products concerned at the time of next repair, next preventive maintenance visit or after a customer complaint.
When an ESI is issued under Code 2, there is no fixed timescale for effecting modifications. However, progress reports must be supplied to SBKR by means of the document described in Annex A (F179).
Must submitt the formal completion report to the competent authorities if applicable.

SBKR:
Is responsible to audit that all ESI code 1 have been performed timely (by means of a document audit: all annexes A or equivalent have been returned and are completed) and to ensure that adequate measures are taken to complete the remaining ones.

4.3 Technical Bulletin (TB)

SBKR
Must prepare the TB in the english language using the form and the contents described in Annex D.

Must use accredited design and production documents. Documents drawn up on the purpose (such as diagrams) may also be attached to the TB, if necessary.

If applicable, the parts list (kit specification) must always be attached to the TB.

The validation section of the document (Annex D) must be signed at the foot of the first page by the designated persons (SBKR and EL) before being issued. Whilst pending, the document should be marked "provisional".

Shall ensure that the contents of the TB are approved by the QA Manager, the R&D Manager, the Production Manager and the Marketing Manager.

Optional requirements: the form F178 may be used to provide documented evidence of the approval process.

Distributors
Are responsible to consider and implement (as necessary) all the requirements of the TB document.

4.4 Distribution List

SBKR:
Shall establish and maintain a distribution list for MFA, ESI and TB. The distribution list must contain as addresses at least the following:
- Service Manager of each distributor
- General Manager of each distributor
- QA Manager of each distributor.

Shall adjust the distribution list according to distributor or personnel changes.

4.5 Document control

SBKR:
Shall ensure that:
- each MFA, ESI, TB document carries a registration and issue (revision) number.
- registers containing the registration number and short description of all issued MFA, ESI and TB are maintained
- where document re-issue is necessary, the issue number is incremented.
- the original of each document is kept by SBKR and will be retained for 13 years.
- written confirmation from the distributors that the prescribed MFA or ESI code 1 has been implemented are maintained.
- for an adverse incident, the MFA and the confirmation from the distributors are kept in the Adverse Incident File (CAR A File, see QS-RL 070).

5. Associated documents

Annex A	List of units to be modified (F179)
Annex B	Example - MFA (F175)
Annex C	Example - ESI (F176)
Annex D	Example - TB (F177)
Annex E	Approval of MFA, ESI, TB (F178)
QS-RL 100.93.070	Handling and Reporting of Incidents (Kap. 14)

Annex A

PRODUCT NAME **MFA or ESI number**

LIST OF UNITS TO BE MODIFIED BY :

Insert here the name of the Affiliate or Distributor

This form must be returned within x days for a MFA, six months for an ESI code 1 and once a year for an ESI code 2.

UNIT Serial or Lot No.	DATE OF MODIFICATION	COMMENTS	NAME AND STAMP

Stamp of the company

Name of the Service Manager:

Date:

Stamp:

Annex B

MANDATORY FIELD ACTION

LINDE MEDICAL SENSORS AG
Austrasse 25
CH-4051 Basel , Switzerland
Tel.: +41 (0)61 278 81 11
Fax.: +41 (0)61 278 81 81

Product:
Product Number:
Date of Issue:
MFA Ref. No.:
Contact: H.R. Vogt

Priority Code: This is a Mandatory Field Action.
It must be performed within x days.

Problem or
Subject: Identification of the problem or subject
Hazard associated with the product

Cause: How/why the problem occurred (only if appropriate)

Affected Products: Identification of affected products (only if appropriate)

Solution or
Remedy: Description of the solution or how to solve the problem
(return, disposal or correction of the affected product)

Additional
Information: Various information if appropriate like:
- instructions for notification of users
- method of response to the Mandatory Field Action

Caution: Warning relative to safety during product modification if necessary

VALIDATED REFERENCE DOCUMENT				Ref. No.:
Name: J.P. Palma	SBRA	Name: P. Eberhard	Managing Director	
Signature:	Date:	Signature:	Date:	Page: 1 of 1

Annex C

ENGINEERING SERVICE INFORMATION

LINDE MEDICAL SENSORS AG
Austrasse 25
CH-4051 Basel , Switzerland
Tel.: +41 (0)61 278 81 11
Fax.: +41 (0)61 278 81 81

Product :
Part number:
Date of Issue:
ESI Ref. No.:
Contact: H.R. Vogt

Priority Code: Code 1: Mandatory, must be performed within 6 month
Code 2: Should be carried out at the time of next repair, preventive maintenance or visit, or after a customer complaint

Problem or Subject: Identification of the problem or subject

Cause: How/why the problem occurred (only if appropriate)

Affected Products: Identification of affected products

Solution or Remedy: Description of the solution or how to solve the problem (correction of the affected product)

Additional Information: Various information if appropriate like:
- instructions for notification of users
- method of response to the ESI

Caution: Warning relative to safety during product modification if necessary

VALIDATED REFERENCE DOCUMENT				Ref. No.:
Name: H. R. Vogt	SBKR	Name: P. Eberhard	R & D Manager	
Signature:	Date:	Signature:	Date:	Page: 1 of 1

Annex D

TECHNICAL BULLETIN

LINDE MEDICAL SENSORS AG
Austrasse 25
CH-4051 Basel , Switzerland
Tel.: +41 (0)61 278 81 11
Fax.: +41 (0)61 278 81 81

Product :
Part Number:
Date of Issue:
TB Ref. No.:
Contact: H.R. Vogt

TITLE / SUBJECT OF TECH BULLETIN

The Tech Bulletin to be drafted here.

VALIDATED REFERENCE DOCUMENT				Ref. No.:
Name: H. R. Vogt	SBKR	Name: P. Eberhard	R & D Manager	
Signature:	Date:	Signature:	Date:	Page: 1 of 1

Annex E

APPROVAL TO
TECHNICAL BULLETIN
ENGINEERING SERVICE INFORMATION
MANDATORY FIELD ACTION

With reference to the requirements of the procedure 100.93.068 (Management of MFA / ESI / TB) this is the approval form for the attached copy of:

- **TECHNICAL BULLETIN (TB)**
  Ref. No.:
- **ENGINEERING SERVICE INFORMATION (ESI)**
  Ref. No.:
- **MANDATORY FIELD ACTION (MFA)**
  Ref. No.:

For Approval	Signature	Date
R & D Manager		
QA Manager		
Production Manager		
Marketing Manager		

SBKR: Date: